



Ministry of Agriculture, Fisheries and Food

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Replies by 26 October 1994 to:

Ms Chris Elms, MAFF, Room 517, 10 Whitehall Place (East Block), London SW1A 2HH

(Tel: 071 270 8335) (Fax: 071 270 8251)

To: Organisations and Interested Parties
on the attached list

cc: All Chief Environmental Health Officers
in England and Wales

26 July 1994

Dear Sir/Madam

DRAFT DAIRY PRODUCTS (HYGIENE) REGULATIONS 1994

1. These draft regulations implement Directive 92/46 on milk hygiene and Directive 92/47 on the conditions for granting temporary and permanent derogations from specific requirements of Directive 92/46. As part of the Government's Food Deregulation Plan they also simplify and consolidate the milk hygiene provisions in existing milk and dairies regulations in England and Wales. Separate but similar regulations have been prepared for Scotland and Northern Ireland and will be issued for public consultation shortly.

2. The regulations cover the production and placing on the market of raw milk, heat treated milk and milk based products from cows, sheep, goats and buffaloes. The EC requirements specify:

- hygiene conditions which dairy farms (farms producing cows, sheep, goat and buffalo milk) must meet in order to be registered by MAFF (ADAS);
- hygiene conditions which dairy product processing establishments must meet in order to be approved by 'food authorities' ie. Local Authority Environmental Health Officers;
- standards for raw milk and microbiological standards for dairy products;



- that products from approved establishments must carry an EC health mark on the wrapping (unless they are subject to a temporary derogation under Directive 92/47 restricting them to the national market);
- conditions for packaging, labelling, transport and storage;

In addition the regulations include a few provisions from existing legislation which following review, have been retained and/or extended mainly on public health grounds:-

- retention of raw drinking milk rules for cows milk - with extension of raw drinking milk standards to raw sheep and goats milk;
- retention of heat-treatment rules for cream and ice cream;
- retention of provisions relating to public health protection from infectious diseases on a temporary basis.
- continuation of chargeable farm hygiene inspections - which will be extended to include holdings where sheep, goat and buffalo milk is produced.

3. Further steps have been taken under the Government's Food Deregulation Plan to simplify milk hygiene legislation by including all the requirements for the retail labelling of milk and milk products in the consolidated and reviewed draft Food Labelling Regulations 1994 which were circulated for comment on 30 March. Similarly all milk sampling requirements will be brought within the scope of the Food Safety (Sampling and Qualifications) Regulations 1990. Two further sets of draft regulations will be issued later to replace and extend current regulations on charges for farm hygiene inspections and to deal with milk and milk product imports.

4. In addition to circulating the draft regulations for comment we also invite comments on the draft of the Code of Practice for enforcement of the Regulations. It is intended that this will be a statutory Code of Practice under S.40 of the Food Safety Act for use by food authorities while enforcing the Regulations. We would also welcome comments on draft guidelines for use by ADAS who will be enforcing certain aspects of the regulations. Provisional IDF reference methods for certain analyses for testing of milk and milk products are currently included in Schedule 11 of the draft regulations but we would welcome views on whether they should be included in the Code of Practice instead.

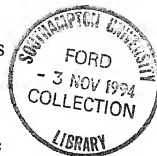
5. In considering proposals for new regulations, the Government places great importance on giving due weight to business' perception of the proposal's likely impact on business. To measure this impact, a Compliance Cost Assessment (CCA) is produced for all such proposals, including new regulations which would be necessary to implement EC directives, and made available to business on request. Therefore, it would be particularly helpful if you could identify and quantify any additional direct or indirect costs (recurring and non-recurring) that would be likely to arise for your sector of business as a result of implementing these proposals. For example,

Recurring costs - sampling, cleaning procedures

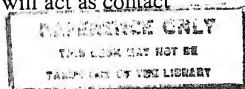
Non-recurring costs - structural refurbishment, new equipment

Our provisional CCA is attached.

6. The regulations are drafted in as simple a language as possible but we have also prepared drafts of three short information leaflets which identify the main issues for producers and processors. We would welcome comments on these documents which we would aim to distribute (in final form) when the regulations become law.



7. We propose that the regulations should not come into effect until after the Council has adopted a series of amendments to Directive 92/46. These amendments, which are currently under discussion in Brussels are shown in the text in bold type. There is also a list attached to the draft regulations showing possible further amendments. Progress on these discussions was reported in my letter of 24 February. Comments on the draft Regulations, the Compliance Cost Assessment, the draft Code of Practice and guidelines and draft information leaflets should be sent to Ms Chris Elms, MAFF, Room 517, 10 Whitehall Place (East Block), London SW1A 2HH by 26 October 1994. Interested parties in Wales should copy their response also to Miss J Matthews, WOAD IB, Government Buildings, Cathays Park, Cardiff CF1 3NQ who will act as contact point in Wales.



8. A number of requirements of Directive 92/46 have already been implemented administratively. Applications for temporary derogations were submitted to the Commission and these have now been agreed. The possibility of granting permanent derogations from certain structural and equipment

requirements (for those milk product processors using less than 300,000 litres of milk per year) is being considered as part of the current exercise by EHOs to approve dairy product processing establishments. Additionally on farm processors who sell their raw milk and raw milk products exclusively direct to consumers are being granted exemptions from the need for approval although they will be subject to the requirements of Schedule 2 Part III and Regulation 13 and relevant standards. No interest has so far been expressed in the exemptions from the raw milk standards and other provisions available to manufacturers of cheeses which ripen over a 60 day period (see Regulation 9) but if any processor wishes to be considered for this, we would be happy to look at this.

9. In order to inform public debate on the issues raised by this consultation letter, MAFF intends to make publicly available, at the end of the consultation period, copies of the responses received. The main MAFF Library at 3 Whitehall Place, London SW1A 2HH (Tel: 0645 335577 - local call rates will be charged) will supply, on request, copies to personal callers or telephone inquiries. It will be assumed, therefore, that your response can be made publicly available in this way, unless you indicate clearly that you wish all or part of it to be excluded from this arrangement.

10. If you have no objection to your response being made available for public examination in this way please supply an additional copy.

11. For those wishing to obtain copies of comments an administrative charge to cover copying and postage will be made. To enable requests to be dealt with efficiently and to avoid undue delay for those calling at the Library in person, it would be appreciated if personal callers could give the Library at least 24 hours notice of their requirements.

Yours sincerely



Elisabeth Owen
Milk and Milk Products Division, Branch C

CIRCULATION LIST FOR EC MILK HYGIENE DIRECTIVE

PLEASE ADVISE US

1. OF ANY ERRORS/OMISSIONS TO THIS LIST
2. OF ANY ERRORS TO THE ADDRESS DETAILS ON THE ENVELOPE
3. IF YOU HAVE NO FURTHER INTEREST IN THIS ISSUE

EITHER BY TELEPHONE 071 270 8253/8255, BY FAX 071 270 8251, ANSAPHONE 071 270 8335 OR BY WRITING TO THE ADDRESS ON THE ATTACHED LETTER

Organisations

AFRC - Institute of Food Research
Amalgamated Master Dairyman
Assembly of Welsh Counties
Association of British Preserved Milk Manufacturers
Association of Cheese Processors
Association of County Councils
Association of District Councils
Association of London Authorities
Association of London Chief Environmental Health Officers
Association of Medical Microbiologists
Association of Metropolitan Authorities
Association of Port Health Authorities
Association of Public Analysts
Association of Unpasteurised Milk Producers and Consumers

Bakery and Allied Trades Association
Barnard & Gooding Goats Milk Ltd
Biscuit, Cake, Chocolate and Confectionery Alliance
British Angora Goat Society
British Association for Chemical Specialities
British Association of Canned and Preserved Food Importers and Distributors
British Diabetic Association
British Dietetic Association
British Essence Manufacturers Association
British Frozen Food Federation
British Goat Society
British Hospitality Association
British Hotel, Restaurants and Caterers Association
British Importers Confederation
British Independent Grocers
British Medical Association
British Nutrition Foundation
British Organic Farmers
British Refrigeration Association
British Retail Consortium
British Sheep Dairying Association
British Soft Drinks Association
British Standards Institution
British Veterinary Association
Butter Council
Butterworths Law of Food and Drugs

Campden Food and Drink Research Organisation
Catering Equipment Manufacturers Association
Chilled Foods Association
Cold Storage and Distribution Federation
Consumers Association
Consumers Committee for E & W (WPW)
Consumers in the European Community Group (UK)
Co-operative Union Limited
Co-operative Wholesale Society
Council of Welsh Districts
Council on Tribunals
Country Landowners Association
Creamery Proprietors Association

Dairy Trade Federation
Dessert and Cake Mixes Association
Direct Sellers Co-operative Ltd

Environmental Health Advisory Services
European Food Law Association

Farmers Union of Wales
Farm Holiday Bureau
Farmhouse Cheesemakers Ltd
Federation of Wholesale Distributors
Food and Drink Federation
Food and Drink Federation (Mr Turner)
Food Commission
Food From Britain
Food Manufacturers Federation
Freight Transport Association Ltd

Goat Advisory Bureau
Goat Veterinary Society
Guild of Food Writers

Health Food Manufacturers Association
Hotel Catering and Institutional Management Association

Ice Cream Alliance
Ice Cream Federation
Independent Food Retailers Confederation
Independent Milk Producers & Processors
Infant and Dietetic Foods Association
Institute of Food Science and Technology
Institute of Grocery Distributors
Institute of Refrigeration
Institute of Trading Standards Administration
Institution of Environmental Health Officers

Leatherhead Food Research Association
Liquid Food Carton Manufacturers Association
Local Authorities Co-ordinating Body on Trading Standards
London Boroughs Association
Long Ashton Research Association

Margarine and Shortening Manufacturers Association
Milk Marketing Board

National and Local Government Officers Association
National Association of Master Bakers
National Association of Speciality Food and Drink Producers
National Catering Federation
National Consumer Council
National Dairy Council
National Dairymen's Association
National Dairy Producers' Association
National Farmers' Union
National Federation of City Farms
National Federation of Consumer Groups
National Federation of Women's Institutes
National Joint Council for Local Authorities
National Office of Animal Health
National Sheep Association

Public Health Laboratory (Dorchester)
Public Health Laboratory Service (Colindale)
Public Health Laboratory Service (Reading)

Quality Milk Producers Ltd

Refrigeration Industry Board
Royal Association on British Dairy Farmers
Royal College of Physicians
Royal College of Veterinary Surgeons
Royal Institute of Public Health and Hygiene
Royal Society of Health
Royal Veterinary College
Rutland Goats

Sheep Veterinary Society
Society of Dairy Technology
Soil Association
Specialist Cheesemakers Association (Mr Curtis)
Specialist Cheesemakers Association (Thames Ditton)
Stilton Cheese Makers Association

Tenant Farmers Association
Trade Union Congress

UK Association of Frozen Food Producers
UK Cheese Guild
UK Dairy Association
UK Home Economics Federation
UK Provision Trade Federation

Vegetarian Society
Veterinary Public Health Association

Womens Farming Union

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Individuals And Companies

Bayer, Mr A
Jones, Ms F
Marston, Mr D
Newman, Mrs J
Smith, Ms S
Wells, Ms A

ADAS, Cambridge: Holmes, Mr J
ADAS, Reading: Hurst, Mr M
AM Consultants: Mettler, Mr A E
Anchor Foods Ltd: Marshall, Mr R
Bombay Halwa Ltd: Nathan, Mr S
British Airways Health Services: Richards, Miss S
Burgess Salmon: Antingham, Mr M
Dee Dairy Services: Hickinbotham, Miss J
Diversey Ltd: Sutton, Dr J R
Europe for Business: Wittenberg, L
Food Law Group: Murray, Ms M
Goat Nutrition Ltd: Dolby, Mr B
Hall and Son: Hall, Mr
H J Heinz Co Ltd: Collins, Mrs C J
H L Foods Ltd: Baxter, Mr J
Holchem Laboratories: Lim, Mr M
IBSA, Consultant EHO: McNeil, Mr A (3)
Jenkins & Potter: Rawson, Mr
Katsouris Fresh Foods: Chand, Mr R
Kilco Dairyfarm Chemicals Ltd: Jones, Mr C P
Kraft Jacobs Suchard: Johnson, Mr R
Law Laboratories: Goodfellow, Ms S
Law Laboratories: Robinson, Ms V
Leworthy Mill: Price, Mr and Mrs
Marks and Spencer: Mitchell, Mr R
Marlow, Wade and Partners: Metcalfe, Mr
Neals Yard Dairy (SCA): Hodgson, Mr R
Nestle UK Ltd: Craddock, Mr N
North Wiltshire District Council: Inkpen, Mr
Peteen Home Farm: Mason, Mr Pete M
Philpot Foods Ltd: Metcalf, Mr R
Pinsent & Co: Jarvis, Miss S
Restormel Borough Council: Hooton, Mr R J
St Ivel: Ross, Mr R

Seaways Services: Shaw, Mrs J
Silclear Ltd: Carey, Mrs J
Sleight Farm: Holbrook, Dr M
Tesco Stores Ltd: Edwards, Mr S
Tetrapack UK
Thorne ITEC: Pain, Miss P
United Transport (UK Ltd)
University of Dundee: Senior, Dr
University of Humberside, School of Food, Fisheries and Environmental Studies: Latus, Mr M G
Water Farm Goat Centre: Mowlem, Mr A
Whitehouse Consultancy: White, Mr N
Woodbridge Farm Partnership: Davies, Mr M

STATUTORY INSTRUMENTS

1994 No.
FOOD
MILK AND DAIRIES
The Dairy Products (Hygiene) Regulations 1994

INDEX
PART I
PRELIMINARY

REGULATION

1. Title and commencement
2. Interpretation
3. Exemptions

PART II
REGISTRATION AND USE OF PRODUCTION HOLDINGS

4. Registration
5. List of production holdings

PART III
APPROVAL AND USE OF DAIRY ESTABLISHMENTS

6. Approvals
7. List of dairy establishments

PART IV
CANCELLATION OF REGISTRATIONS AND REVOCATION OF APPROVALS

8. Cancellation and revocation

PART V
CONDITIONS FOR THE HANDLING AND MARKETING OF DAIRY
PRODUCTS

9. General conditions
10. Methods of analysis
11. Storage, transport, wrapping and labelling conditions
12. Restrictions on the sale of raw cows' drinking milk

PART VI
CONDITIONS RELATING TO ALL DAIRY ESTABLISHMENTS

13. Duties of occupier

PART VII
TRANSITIONAL PROVISIONS RELATING TO DAIRY FARMS AND DAIRY
ESTABLISHMENTS

14. Dairy farms
15. Derogation under Directive 92/47

PART VIII
SUPERVISION, PENALTIES AND ENFORCEMENT

16. Supervision by the Minister and the approving authority
17. Information to be provided by food authorities
18. Offences and penalties
19. Enforcement
20. Authorisation to derogate
21. Application of various sections of the Act
22. Revocations
23. Consequential amendments

SCHEDULES

- | | |
|------------|--|
| Schedule 1 | Conditions for registration of production holdings |
| Schedule 2 | Conditions for approval of dairy establishments |
| Schedule 3 | Requirements for raw milk |

Schedule 4	Requirements for drinking milk
Schedule 5	Requirements for milk used for the manufacture of milk-based products
Schedule 6	Requirements for milk-based products
Schedule 7	Storage requirements
Schedule 8	Transport requirements
Schedule 9	Wrapping and packaging
Schedule 10	Labelling and health marking
Schedule 11	Methods of analysis
Schedule 12	Revocations

PART 1

PRELIMINARY

Title and commencement

1.-(1) These Regulations may be cited as the Dairy Products (Hygiene) Regulations 1994 and shall come into force on 1994.

(2) These Regulations shall apply to England and Wales.

Interpretation

2.-(1) In these Regulations, unless the context otherwise requires -
"the Act" means the Food Safety Act 1990;

^(a) 1990 c.16; "the Ministers" is defined in section 4(1) of the Act.

"animals" means cows, ewes, goats or buffaloes;

"another member State" means a member State of the European Community other than the United Kingdom;

"approved" in relation to a dairy establishment means approved by the approving authority in accordance with regulation 6 and approval shall be construed accordingly;

"approving authority" means the food authority for the area within which a dairy establishment is situated;

"authorised officer" means an authorised officer of the Minister or of a food authority, as the case may be;

"batch" means a quantity of dairy products which have been prepared under technologically similar conditions;

"catering establishment" means a restaurant, canteen, club, public house, school, hospital, institution or other establishment (including a vehicle or a fixed or mobile stall) where, in the course of a business, food is prepared for delivery to the ultimate consumer for immediate consumption;

"collection centre" means an establishment where raw milk is collected and where it may be cooled and filtered;

"Council Directive 92/46" means Council Directive 92/46/EEC, laying down the health rules for the production and placing on the market of milk and milk-based products^(a) as amended^(b) to be read with Council Directive 92/47;

"Council Directive 92/47" means Council Directive 92/47/EEC on the conditions for granting temporary and limited derogations from specific Community health rules on the production and placing on the market of milk and milk-based products^(c);

"cream" means that part of cows' milk rich in fat which has been separated by skimming or otherwise;

^(a) OJ No. L268, 14.9.92, p.1.

^(b) Council Directive 92/118/EEC OJ No. L62, 15.3.92, p.49.

^(c) OJ No. L268, 14.9.92, p.33.

"dairy establishment" means any undertaking handling dairy products and is either:-

(a) a standardisation centre, or
any one of the following undertakings operating alone or in combination:-

- (b) a treatment establishment,
- (c) a processing establishment, or
- (d) a collection centre;

"dairy product" means milk or any milk-based product intended for human consumption;

"distributor" means a person who sells drinking milk which is raw cow's milk, produced in a registered production holding other than a production holding of which such person is the occupier;

"drinking milk" means milk intended for human consumption and in relation to drinking milk which is cows' milk, has the meaning assigned to it by Article 3(1) of Council Regulation (EEC) No. 1411/71^(a) as amended^(b) laying down additional rules on the common market organisation in milk and milk products for drinking milk;

"establishment" in Part II of Schedule 2 means a treatment establishment or a processing establishment;

"farm premises" includes the production holding and any processing establishment or other buildings situated on the farm occupied by the occupier of a registered production holding as a single farm;

"handling" includes preparing, processing, packaging, wrapping or re-wrapping in the course of a business;

"health mark" means a mark applied in accordance with regulation 11 and of a kind and in a manner as set out in Schedule 10;

^(a) OJ No. L148, 3.7.71, p.4 (OJ/SE 1971 vol. II, p.412), as read with the corrigendum at OJ No. L107, 24.4.76, p.22.

^(b) The relevant amending instruments are Council Regulation (EEC) No. 566/76 (OJ No. L67, 15.3.76, p.23), Commission Regulation (EEC) No. 222/88 (OJ No. L28, 1.2.88, p.1) and Council Regulation (EEC) No. 2138/92 (OJ No. L214, 30.7.92, p.6).

"heat-treatment" means any treatment of a dairy product involving heating that causes, immediately after such treatment, a negative reaction to the phosphatase test;

"heat-treated milk" means milk obtained by heat-treatment;

"heat-treated drinking milk" means either drinking milk intended for sale to the ultimate consumer or to institutions, obtained by heat-treatment and presented as pasteurised, UHT or sterilised milk, or milk treated by pasteurisation at the request of the individual consumer for sale in bulk;

"hermetically sealed container" means a container which, when sealed, is impervious and is intended to protect its contents against the entry of micro-organisms during and after heat-treatment;

"ice-cream" means -

- (a) except in Part V and VI of Schedule 6, any ice-cream which is a milk-based product, and
- (b) in Parts V and VI of Schedule 6, ice-cream made from cows' milk;

"limited production" in relation to the production of milk-based products means such production -

- (a) in a low capacity dairy establishment; or
- (b) by means of a separate circuit^(a) within any dairy establishment where heat-treated drinking milk or liquid milk-based products are manufactured and where the annual usage of milk or milk-based products converted to the equivalent in liquid milk for the production by such separate circuit does not exceed 300,000 litres;

"low capacity dairy establishment" means a dairy establishment whose annual usage of milk or milk-based products converted to the equivalent in liquid milk for the manufacture of milk-based products does not exceed 300,000 litres;

"milk" means the milk of cows, ewes, goats or buffaloes intended for human consumption;

^(a) The expression "separate circuit" is used in Article 3(2) of Council Directive 92/47/EEC.

"milk-based products"^(a) means -

- (a) milk products exclusively derived from milk to which other substances necessary for their manufacture may have been added, provided that those substances do not replace in part or in whole any milk constituent, and
- (b) composite milk products of which no part replaces or is intended to replace any milk constituent and of which milk or a milk product is an essential part either in terms of quantity or for characterisation of the product,

intended for human consumption;

"milk for the manufacture of milk-based products" means raw milk for processing or liquid or frozen milk obtained from raw milk, whether or not it has undergone an authorised physical treatment, such as heat treatment or thermisation, or is modified in its composition, provided that these modifications are restricted to the addition or removal, or both, of natural milk constituents;

"occupier" means any person carrying on the business of a producer or handler of dairy products or his duly authorised representative;

"packaging" means the placing of one or more wrapped or unwrapped dairy products in a container, as well as the container itself;

"pasteurisation" means the process of treating milk in accordance with paragraph 2(a) of Part III of Schedule 4;

"pasteurised milk" means milk obtained by pasteurisation;

"potable water" means water within the meaning of Council Directive 80/778/EEC^(b) as amended^(c) relating to the quality of water intended for human consumption;

"processing" includes manufacturing as well as operations such as slicing;

^(a) See Article 2(4) of Council Directive 92/46/EEC.

^(b) OJ No. L229, 30.8.80, p.11.

^(c) The relevant amending instrument is Council Directive 81/858/EEC (OJ No. L319, 7.11.81, p.19).

"processing establishment" means an establishment where any dairy product is either treated, processed and wrapped or undergoes one or more of those handling activities;

"product licence" means a product licence granted under the Medicines Act 1968^(a);

"production holding" means premises at which one or more milk-producing cows, ewes, goats or buffaloes are kept;

"raw" in relation to milk intended for human consumption means milk produced by the secretion of the mammary glands of one or more cows, ewes, goats or buffaloes, which has not been heated beyond 40°C or undergone any treatment which has an equivalent effect;

"registration" in relation to a production holding means registration in accordance with regulation 4 and "registered" shall be construed accordingly;

"sell" includes offer, expose, advertise or have in possession for sale;

"shop premises" means premises (including vehicles) from which any food is sold to the ultimate consumer;

"standardisation centre" means an establishment which is not attached to a collection centre or to a treatment or processing establishment and where raw milk may be skimmed or its natural constituents modified;

"sterilised milk" means milk which has been treated in accordance with paragraph 4 of Part III of Schedule 4;

"thermisation" means the process of treating milk in accordance with the requirements specified in paragraph 1(b) of Part II of Schedule 5;

"thermised milk" means milk intended for human consumption obtained by thermisation;

"treatment establishment" means an establishment where milk is heat-treated;

"UHT milk" means milk which has been treated in accordance with paragraph 5(a) of Part III of Schedule 4;

^(a) 1968 c.67.

"ultimate consumer" means any person who buys otherwise than -

- (a) for the purpose of resale;
- (b) for the purposes of a catering establishment; or
- (c) for the purposes of a manufacturing business,

"veterinary surgeon" has the meaning assigned to it by the Medicines (Medicated Animal Feeding Stuff) (No. 2) Regulations 1992^(a);

"veterinary written direction" has the meaning assigned to it by the Animals, Meat and Meat Products (Examination for Residues - Maximum Residue Limits) Regulations 1991^(b);

"withdrawal period" in relation to Part I of Schedule 3 means the period specified in a current product licence relating to a product administered to the animal, or (in the absence of any such specification) specified in a prescription or a veterinary written direction given by a veterinary surgeon in respect of the administration of the product, which is required to elapse from the cessation of the administration of the product to the taking of the milk for human consumption;

"wrapping" means the protection of dairy products by the use of an initial wrapping or initial container in direct contact with the products concerned as well as the initial wrapper or initial container itself.

(2) Other expressions used in these Regulations have, in so far as the context admits, the same meaning as in Council Directive 92/46.

(3) Except in so far as the context otherwise requires, any reference in these Regulations to a numbered regulation or Schedule shall be construed as a reference to the regulation or Schedule bearing that number in these Regulations.

Exemptions

3.-(1) These Regulations shall not apply to -

^(a) S.I. 1992/1520.

^(b) S.I. 1991/2843 to which there are amendments not relevant to these Regulations.

- (a) any production holding or dairy establishment producing or handling dairy products exclusively for the consumption of the occupier of such production holding or dairy establishment;
 - (b) any production holding or dairy establishment producing or handling dairy products exclusively for the supply by such occupier -
 - (i) otherwise than on sale, and
 - (ii) other than in the course of business;
 - (c) any person engaged in the production or handling of dairy products described in sub-paragraphs (a) and (b) above;
- (2) Subject to paragraphs (3) and (4) below these Regulations shall not apply -
- (a) in relation to the handling of any dairy products in any catering establishment or shop premises;
 - (b) in relation to the sale of any dairy products from any catering establishment or shop premises; or
 - (c) to any person engaged in the selling or handling of dairy products described in sub-paragraphs (a) and (b) above.
- (3) Notwithstanding the exemption in paragraph (2) above, the requirements of Parts II to VI of Schedule 6 shall apply in relation to the handling for sale of any cream or ice-cream in any catering establishment or shop premises.
- (4) Notwithstanding the exemption in paragraph (2) above, the requirements of regulation 12 shall apply in relation to any catering establishment or shop premises selling drinking milk which is raw cows' milk.
- (5) Regulation 6 shall not apply in relation to any processing establishment which comprises part of a farm premises from which is carried on the business of selling or handling -
- (a) any raw milk wrapped in that processing establishment; or
 - (b) any raw milk-based product made from raw milk produced on the farm premises,
- where such sales are made direct to the ultimate consumer exclusively.

(6) Regulation 11(1)(b) and (d) shall not apply in relation to the sale of any raw milk or milk-based product referred to in paragraph (5) above.

(7) Notwithstanding paragraphs (5) and (6) above the occupier of a processing establishment referred to in paragraph (5), shall -

- (a) ensure that the requirements of regulation 6(1) read with Part III of Schedule 2; and
- (b) ensure that the requirements of regulation 13(1)(a), (b)(i), (ii), [(iii), (iv), (v)] (f), (g) and (h) and (2)

are complied with in that processing establishment.

PART II

REGISTRATION AND USE OF PRODUCTION HOLDINGS

Registration

4.-(1) No person shall use any premises as a production holding for the production of raw milk unless those premises -

- (a) comply with the appropriate requirements of Schedule 1; and
- (b) are registered in accordance with the provisions of paragraph (3)(a) below, or deemed to be registered in accordance with regulation 14.

(2) No person shall at any time -

- (a) despatch from any registered production holding any raw milk which does not comply with the provisions of these Regulations;
- (b) despatch to another member State, or any part of the British Islands, any raw milk except raw milk produced on a registered production holding.

(3) The Minister on application made to the Minister under this regulation shall -

- (a) register the premises to which the application relates as a production holding if the Minister is satisfied that both the premises and the arrangements at those premises for use as a production holding are adequate



to comply with the requirements of Schedule 1 and paragraphs 1 and 2 of Schedule 7;

- (b) refuse to register the premises as a production holding if the Minister is not so satisfied.

(4) Each application for registration under this regulation shall be made in writing to the Minister by the occupier of, or a person proposing to occupy, the production holding to which the application relates.

(5) The Minister shall, not later than 28 days after receipt of the application referred to in paragraph (4) above, notify the applicant in writing of the Minister's decision on that application and of the reasons for any refusal to register such production holding, together with the details specified in section 37(6) of the Act.

(6) Any person who is aggrieved by the decision of the Minister not to grant a registration or by the imposition of any condition specified by the Minister, may appeal against that decision in accordance with the provisions of sections 37(3) to (5) inclusive of the Act.

(7) Any registration granted in respect of any production holding under this regulation shall be subject to the condition that any alteration to that production holding shall comply with the requirements of Schedule 1 and paragraphs 1 and 2 of Schedule 7, if appropriate.

(8) Without prejudice to sections 9 to 12 of the Act, where the Minister has refused a registration under this regulation, a person who both prior to the commencement of these Regulations and immediately before such refusal had been using any premises for the production of raw milk, may continue to use such premises for that purpose, subject to any reasonable conditions imposed by the Minister for the protection of public health, until the time for appeal has expired and, if an appeal is lodged, until the appeal is finally disposed of or abandoned.

(9) The Minister shall be entitled to -

- (a) inspect any premises in respect of which an application has been made to register such premises as a production holding, prior to registering such premises as a production holding;
- (b) inspect any registered production holding to ensure that the requirements of these Regulations are being complied with.

List of production holdings

5.-(1) The Minister shall allot a registration number to each registered production holding, including any premises deemed to be registered by regulation 14, and keep a list of such production holdings.

(2) Any such production holding which ceases to be used as a production holding shall be removed from the list kept by the Minister pursuant to paragraph (1) above.

PART III

APPROVAL AND USE OF DAIRY ESTABLISHMENTS

Approvals

6.-(1) No person shall use any premises as a dairy establishment, unless those premises -

- (a) comply with the appropriate requirements of Schedule 2; and
- (b) are approved in accordance with the provisions of paragraph (3)(a) below.

(2) No person shall -

- (a) despatch from any approved dairy establishment any dairy products which do not comply with the provisions of these Regulations;
- (b) despatch to another member State or any part of the British Islands, any dairy products except those produced in an approved dairy establishment.

(3) Subject to paragraph (7) below, an approving authority on application made to that authority under this regulation shall -

- (a) approve the premises to which the application relates as a dairy

establishment, if that authority is satisfied that -

- (i) in the case of a collection centre, the arrangements at those premises comply with the requirements of Parts I and III of Schedule 2 and with the appropriate requirements of section B of Part II of that Schedule;
 - (ii) in the case of a standardisation centre, the arrangements at those premises comply with the requirements of Parts I and III of Schedule 2 and with section C of Part II of that Schedule;
 - (iii) in the case of a processing establishment, the arrangements at those premises comply with the requirements of Parts I and III of Schedule 2 and with the appropriate requirements of section A of Part II of that Schedule;
 - (iv) in the case of a treatment establishment, the arrangements at those premises comply with the requirements of Parts I and III of Schedule 2 and with the appropriate requirements of section A of Part II of that Schedule; and
 - (v) the arrangements at the dairy establishment are adequate to enable the occupier to comply with the requirements of regulation 13(1);
- (b) refuse to approve the premises as a dairy establishment if that authority is not so satisfied.

(4) Each application for an approval under this regulation shall be made in writing to the approving authority by the occupier of, or a person proposing to occupy, the dairy establishment to which the application relates.

(5) The approving authority shall, not later than 28 days after receipt of the application referred to in paragraph (4) above, notify the applicant in writing of its decision on that application and of the reasons for any refusal to approve such dairy establishment together with the details specified in section 37(6) of the Act.

(6) Any person who is aggrieved by a decision of the approving authority not to grant an approval or by the imposition of any condition specified by the approving authority,

may appeal against that decision in accordance with the provisions of sections 37(3) to (5) inclusive of the Act.

(7) Any approval granted in respect of any dairy establishment under this regulation shall be subject to the condition that any alteration to the establishment shall comply with the requirements of Schedule 2, if appropriate.

(8) The approving authority may approve as a dairy establishment any low capacity dairy establishment which may not comply with any or all of the requirements of paragraphs 2 and 3 of Part I and section A of Part II of Schedule 2.

(9) Without prejudice to sections 9 to 12 of the Act, where the approving authority has refused an approval under this regulation, a person who both prior to the coming into force of these Regulations and immediately before such refusal had been using any premises for the handling of dairy products, may continue to use such premises for that purpose, subject to any reasonable conditions imposed by the approving authority for the protection of public health, until the time for appeal has expired and, if an appeal is lodged, until the appeal is finally disposed of or abandoned.

(10) The approving authority shall be entitled to -

- (a) inspect any premises in respect of which an application has been made for approval as a dairy establishment, prior to approving such premises as a dairy establishment;
- (b) inspect any approved dairy establishment to ensure that the requirements of these Regulations are being complied with.

List of dairy establishments

7.-(1) The approving authority shall allot an approval number to each dairy establishment which that authority has approved and shall keep a list of those dairy establishments.

(2) Any approved dairy establishment which ceases to be used as a dairy establishment shall be removed from the list kept by the approving authority pursuant to paragraph (1) above.

PART IV

CANCELLATION OF REGISTRATIONS AND REVOCATION OF APPROVALS

Cancellation and revocation

8.-(1) The Minister may cancel a registration granted by the Minister under regulation 4, or granted by virtue of regulation 14 in respect of any production holding if, after an inspection of, or an inquiry into, the operation of the production holding, the Minister is satisfied that in respect of that production holding -

- (a) there is an obvious failure to comply with these Regulations;
- (b) there are obstacles to an adequate inspection of the production holding; or
- (c) the premises have ceased to be used as a production holding.

(2) An approving authority may revoke an approval granted by that authority under regulations 6 or 15 in respect of any dairy establishment if, after an inspection of, or an inquiry into, the method of operation of that dairy establishment, it is satisfied that in respect of that dairy establishment -

- (a) there is an obvious failure to comply with these Regulations;
- (b) there are obstacles to an adequate inspection of the dairy establishment; or
- (c) the premises have ceased to be used as a dairy establishment.

(3) The Minister or the approving authority shall give the occupier of the premises notice in writing -

- (a) of the decision by the Minister or the approving authority, as the case may be, to cancel the registration of a production holding or to revoke the approval of a dairy establishment;
- (b) of the date on which the cancellation or revocation is to take effect; and
- (c) of the reasons for cancellation or revocation.

(4) An approval may not be revoked under paragraph (2)(a) or (b) above unless there is in force in relation to the premises -

- (a) a prohibition order under section 11 of the Act; or
- (b) an emergency prohibition order under section 12.

(5) Any person who is aggrieved by the refusal or cancellation of a registration, or the refusal or revocation of an approval may appeal to a magistrates' court.

(6) Sections 37(3) to (6) of the Act shall have effect in relation to an appeal under this regulation as they have effect in relation to an appeal under that section but with the omission -

- (a) of the references to appeals for which provision is made by regulations under section 37(2); and
- (b) of subsection 5(b) and the word "or" immediately preceding it.

PART V

CONDITIONS FOR THE HANDLING AND MARKETING OF DAIRY PRODUCTS

General conditions

9.-(1) Subject to paragraph (11) below and regulation 15, no person shall sell for human consumption any raw milk, thermised milk, heat-treated drinking milk, heat-treated milk intended for the manufacture of milk-based products or milk-based products unless -

- (a) it originates from a registered production holding or an approved dairy establishment which complies with the requirements, as appropriate, set out in Schedules 1 and 2;
- (b) it complies with the requirements, as appropriate, set out in Schedules 3, 4 and 5;
- (c) the occupier of the dairy establishment has complied with the provisions of regulation 13 in relation to it;
- (d) in particular it complies with the relevant conditions specified in paragraphs (2), (3), (4), (5) or (6) below, as are applicable;
- (e) it complies with paragraphs (7), (8), (9) and (10) below, if applicable;
- (f) it complies with regulation 11.

(2) In the case of raw drinking milk, the relevant conditions to be complied with are those specified in -

- (a) paragraph 1 and 2 of Part I of Schedule 4 and regulation 12, in the case of raw cows' milk, and
- (b) paragraph 1 of Part I of Schedule 4, in the case of raw ewes' milk or raw goats' milk.

(3) In the case of thermised milk, the relevant conditions to be complied with are, that -

- (a) it shall be manufactured from raw milk which complies with the requirements of paragraph (1)(a), (b) and (c) above; and
- (b) where the thermised milk is intended for the manufacture of milk-based products, it complies with the requirements of paragraph 1 of Part II of Schedule 5.

(4) In the case of heat-treated drinking milk, the relevant conditions to be complied with are, that -

- (a) it shall be manufactured from raw milk or thermised milk which complies with paragraph (1)(a), (b) and (c) above;
- (b) it shall be manufactured from other heat-treated drinking milk which complies with the appropriate requirements of paragraphs 1 to 7 of Part III of Schedule 4; or
- (c) it shall be manufactured from a mixture of the milks specified in subparagraphs (a) and (b) above.

(5) In the case of heat-treated milk intended for the manufacture of milk-based products, the relevant conditions to be complied with are those specified in Parts III and IV of Schedule 5.

(6) In the case of milk-based products, the relevant conditions to be complied with are those specified in Schedule 6 and that it shall be manufactured from -

- (a) raw milk or thermised milk which complies with paragraphs (1)(a), (b) and (c) and (3)(b) above, as appropriate;

- (b) heat-treated drinking milk which complies with paragraph (4)(b) above; or
- (c) heat-treated milk (not being heat-treated drinking milk) which complies with paragraph (5) above.

(7) No person shall sell any raw cows' milk for human consumption to any catering establishment without heat-treatment of such milk.

(8) No person shall sell any thermised cows' milk for human consumption to the ultimate consumer without heat-treatment of such milk.

(9) No person shall sell any dairy products which come from a declared infected area unless the milk used in the processing of such dairy products has undergone pasteurisation.

(10) For the purposes of paragraph (9) above, an "infected area" has the same meaning as in the Foot and Mouth Diseases Order 1983^(a).

(11) In the case of cheese with a period of ageing or ripening of at least sixty days and which complies with Part I of Schedule 6, it shall not be necessary for such cheese to -

- (a) be made from raw milk complying with paragraphs 2, 3 and 4 of Part II of Schedule 3,
- (b) be prepared in an approved dairy establishment, or
- (c) comply with the provisions of regulation 11(1)(c) below.

Methods of analysis

10. For the purposes of these Regulations the methods of analysis and testing of dairy products specified in Schedule 11 shall be used in relation to the requirements referred to in that Schedule.

Storage, transport, wrapping and labelling conditions

11.-(1) Dairy products intended for sale shall -

- (a) be handled, stored and transported in accordance with Schedules 7 and 8;

^(a) S.I. 1983/1950 amended by S.I. 1993/3119.

- (b) in the case of any heat-treated drinking milk or milk-based products [transported in bulk,] be accompanied during such transportation by a commercial document in accordance with the requirements of Part III of Schedule 8;
- (c) subject to regulation 9(11) above, be wrapped and packaged in accordance with the requirements of Schedule 9; and
- (d) subject to paragraphs (4) and (5) below and regulation 15, be marked with a health mark and labelled in accordance with the appropriate requirements of Schedule 10.

(2) Any person who receives dairy products together with the commercial document referred to in paragraph (1)(b) above, shall keep that document for a period of at least one year after the date of such receipt and make it available for inspection at the request of an authorised officer.

(3) No person shall use on any dairy product any mark so resembling a health mark in such a way as to be likely to suggest that the product has been produced in accordance with these Regulations.

(4) Without prejudice to the requirements in paragraph (1)(a) and (b) above, an occupier may until 1st January 1995*, use on his dairy products any packaging or wrapping which may not comply with the requirements of Part II of Schedule 10 (health mark).

(5) No person shall import into England and Wales for sale for human consumption any dairy products except in accordance with the following paragraphs -

- (a) where dairy products are manufactured in any other member State, or any part of the British Islands other than England and Wales, they shall comply with the relevant legislation in that other member State or that part of the British Islands which implements Council Directive 92/46;
- (b) where dairy products are manufactured in any third country they shall be accompanied by a certificate as specified in Articles 23(2)(b) and 25(1) of Council Directive 92/46.

(6) In paragraph (5)(a) above, relevant legislation shall include any administrative provisions enacted in another member State or part of the British Islands to comply with Council Directive 92/46.

Restrictions on the sale of raw cows' drinking milk

12.-(1) No person shall sell drinking milk which is raw cows' milk intended for sale as drinking milk, except in accordance with the following provisions of this regulation.

(2) An occupier of a registered production holding may sell such milk to the ultimate consumer or to a distributor, at or from the farm premises where the animals from which such milk has been obtained are maintained .

(3) A distributor may sell such milk -

- (a) in the containers in which he receives such milk with the fastenings of such containers unbroken;
- (b) from a vehicle which is lawfully used as shop premises; and
- (c) direct to the ultimate consumer.

PART VI

CONDITIONS RELATING TO ALL DAIRY ESTABLISHMENTS

Duties of occupier

13.-(1) Subject to paragraph (3) below, the occupier of any approved dairy establishment shall -

- (a) take all necessary measures to ensure that, at all stages of handling of dairy products at that dairy establishment, the appropriate requirements of these Regulations are complied with; and
- (b) carry out his own checks to ensure -
 - (i) that critical points in the dairy establishment relative to the processes used there are identified;

- (ii) that methods (which are acceptable to the approving authority) for monitoring and controlling such critical points are established;
 - (iii) that appropriate tests are carried out to detect any residues of substances having pharmacological or hormonal action, and of antibiotics, pesticides, detergents and other substances which are harmful to human health or which might alter the organoleptic characteristics of dairy products or make their consumption harmful to human health if those residues exceed permitted tolerance limits;
 - (iv) that appropriate tests are carried out to detect the presence of any added water in milk in accordance with Part III of Schedule 3 and as required by paragraph 1 of Part III of Schedule 4;
 - (v) that samples taken for the purpose of checking the cleaning and disinfection methods, or for the purpose of checking compliance with the standards for dairy products prescribed in Schedules 3, 4, 5 and 6, are analysed and examined as appropriate in a laboratory the use of which for such purposes is acceptable to the approving authority;
- (c) insofar as it is reasonable and practicable to do so, keep a record in permanent form of the matters specified in paragraph (b) above for a period -
- (i) of not less than two months, calculated from the end of the minimum durability indication or "use by" date on such product, in the case of any dairy product which cannot be stored at ambient temperature, and
 - (ii) of not less than two years, calculated from the date to which such record relates, in the case of any other dairy product;
- (d) upon demand by an authorised officer produce or cause to be produced any record the occupier is required to keep by paragraph (c) above for

inspection by such authorised officer and allow him to take copies and make extracts from it;

- (e) ensure the proper administration and control of the health mark;
- (f) ensure that the approving authority is notified immediately when a laboratory examination of samples or any other information in the occupier's possession or under his control reveals a serious health risk;
- (g) furnish the approving authority with such information and assistance as it may reasonably request so as to enable it to take such action as it may consider necessary under these Regulations or the Act;
- (h) ensure, in the event of an immediate human health risk, the withdrawal from the market of the quantity of dairy products obtained under technologically similar conditions and likely to present the same risk; and also ensure that any quantity of the dairy product so withdrawn is held under the supervision and control of the approving authority until it is destroyed, or used for purposes other than human consumption, or, with the agreement of the approving authority, reprocessed in a manner appropriate to ensure its safety for human consumption.

(2) The occupier of any dairy establishment shall ensure that employees are adequately trained for the type of manufacture being undertaken in that dairy establishment.

(3) Where raw milk is purchased from a production holding by any person other than the occupier of an approved dairy establishment or a distributor, for re-sale as milk, such person shall ensure that the following obligations in relation to that milk are complied with:-

- (a) the carrying out of appropriate tests to detect any residues of substances as specified in paragraph (1)(b)(iii) above;
- (b) the carrying out of appropriate tests to detect the presence of added water in accordance with Part III of Schedule 3;

- (c) the taking of samples for the purpose of checking compliance of the milk with the standards for dairy products prescribed in Schedule 3;
- (d) the requirements specified in paragraphs (1)(c) to (h) above.

PART VII

TRANSITIONAL PROVISIONS RELATING TO DAIRY FARMS AND DAIRY ESTABLISHMENTS

Dairy farms

14. Any production holding which is both registered as a dairy farm before the coming into force of these Regulations, pursuant to the Milk and Dairies (General) Regulations 1959^(a) and is in operation as such on the date before the date these Regulations come into force, shall be deemed to be premises registered under and subject to the provisions of these Regulations, as a production holding.

Derogation under Directive 92/47

15.-(1) Notwithstanding the requirements of regulation 6(3) and until 31st December 1997 an approving authority may approve a dairy establishment which does not comply with any or all of the requirements of Schedule 2, in accordance with Article 2 of Council Directive 92/47.

(2) Dairy products produced in a dairy establishment approved in accordance with paragraph (1) above shall not -

- (a) bear a health mark, or
- (b) be intended for export to another member State.

(3) Notwithstanding the prohibition in regulation 9(1)(a) and until 31st December 1997 -

^(a) S.I. 1959/277 to which there are amendments not relevant to these Regulations.

- (a) where an occupier of a dairy establishment is unable to obtain supplies of milk which complies with the requirements of paragraphs 2, 3 and 4 of Part II of Schedule 3, such occupier may sell any dairy products produced in that dairy establishment subject to the conditions specified in paragraph (5) below; and
 - (b) where the occupier of an approved dairy establishment is unable to obtain supplies of milk which complies with the requirements of paragraphs 2, 3 and 4 of Part II of Schedule 3 for the production of some of the dairy products produced in that approved dairy establishment, being a part of the total quantity of dairy products produced in that approved dairy establishment, such occupier may sell the dairy products produced with such milk subject to the conditions specified in paragraph (4) below and his complying with the further conditions specified in paragraph (5) below.
- (4) The conditions referred to in paragraph (3)(a) and (b) above are that the dairy products in question shall not -
- (a) be marked with a health mark, or
 - (b) be intended for export to another member State.
- (5) The further conditions referred to in paragraph (3)(b) above are that the occupier shall -
- (a) take all necessary measures, under the supervision of the approving authority, to ensure that any raw milk [,heat-treated drinking milk] or milk-based products which do not comply with the requirements in Part II of Schedule 3 specified in that paragraph are treated or processed in a clearly separated place or at a completely different time from dairy products which comply with those requirements and which are intended for export to another member State;
 - (b) show to the satisfaction of the approving authority that the measures taken by him to keep a constant check on the use of the health mark are adequate

to ensure that it cannot be mistakenly applied to the products referred to in preceding sub-paragraph (a);

- (c) keep at the disposal of the approving authority a record of the raw materials used and of the dairy products produced at that establishment which will allow the two separate circuits to be verified.

(6) In paragraph (1) and (2) above, "dairy establishment" shall include a part of a dairy establishment, and "dairy products" shall mean the dairy products, in respect of which a derogation has been granted in accordance with Article 2 of Directive 92/47.

PART VIII

SUPERVISION, PENALTIES AND ENFORCEMENT

Supervision by the Minister and the approving authority

16.-(1) The Minister shall be responsible for the supervision of any production holdings registered by the Minister in accordance with regulation 4 and those deemed to be registered by regulation 14.

(2) The approving authority shall be responsible for the supervision of any dairy establishments approved by that authority in accordance with regulations 6 and 15.

Information to be provided by the approving authorities

17. Every approving authority shall provide the Minister with such information relating to the execution of its functions under these Regulations as the Minister may from time to time require.

Offences and penalties

18.-(1) If any person contravenes or fails to comply with any of the provisions of regulations 4(1), (2), 6(1), (2), 9(1) to (10), 11(1) to (3) and (5), 12, 13 or 15(2), (4) and (5), he shall be guilty of an offence.

(2) If the occupier of any production holding or dairy establishment fails to take all reasonable steps to secure the compliance by any person employed by him or any person admitted to that production holding or dairy establishment with any provision of these Regulations he shall be guilty of an offence.

(3) A person guilty of an offence under paragraph (1) or (2) above shall be liable -

- (a) on summary conviction, to a fine not exceeding the statutory maximum; or
- (b) on conviction on indictment, to a fine or imprisonment for a term not exceeding two years or to both.

Enforcement

19. These Regulations shall be executed and enforced by the food authority within its area or the Minister.

Authorisations to derogate

20. The food authority referred to in regulation 19 may -

- (a) authorise derogation from the requirements as to automatic sealing in the case of limited production specified in paragraph 2 of section A Part II of Schedule 2 and paragraph 4 of Schedule 9, in accordance with paragraph (a) of Chapter V of Annex B and paragraph 3 of Chapter III of Annex C of Council Directive 92/46;
- (b) authorise derogation from the requirements as to equipment specified in paragraph 7(1) of section A of Part II of Schedule 2, in accordance with paragraph (f) of Chapter V of Annex B of Council Directive 92/46;
- (c) authorise derogation from the requirements as to times and temperatures specified in paragraphs 1 and 2 of Part I of Schedule 5, in accordance with paragraph B(1) of Chapter I, Annex C of Council Directive 92/46;
- (d) authorise derogation from the requirements as to temperature for goats' and sheeps' milk-based products specified in paragraph 2 of Schedule 7 and

paragraph 1 of Part I of Schedule 8, in accordance with paragraph A(2) of Chapter III of Annex A of Council Directive 92/46;

- (e) authorise derogation from the requirements as to equipment specified in paragraph 4 of Section A of Part III of Schedule 2, in accordance with paragraph A(3) of Chapter II, Annex B of Council Directive 92/46.

Application of various sections of the Act

21.-(1) The following provisions of the Act shall apply for the purposes of these Regulations as they apply for the purposes of section 8, 14 or 15 of the Act and, unless the context otherwise requires, any reference in them to the Act shall be construed as a reference to these Regulations:-

- (a) section 2 (extended meaning of "sale" etc);
- (b) section 3 (presumption that food is intended for human consumption);
- (c) section 20 (offences due to fault of another person);
- (d) section 21 (defence of due diligence);
- (e) section 30(8) (which relates to documentary evidence);
- (f) section 33 (obstruction etc. of officers);
- (g) section 36 (offences by bodies corporate);
- (h) section 44 (protection of officers acting in good faith).

(2) Section 5(6) (appointment of a person who is not an officer) of the Act shall apply in relation to an appointment by a food authority for the purposes of these Regulations as it applies in relation to matters arising under the Act.

(3) Section 8(3) (which makes presumptions in the case of batches of food) of the Act shall apply to food which it is an offence to sell under these Regulations as it applies to food which fails to comply with food safety requirements.

(4) Section 9 (inspection and seizure of suspected food) of the Act shall apply to food which it is an offence to sell under these Regulations as it applies to food which fails to comply with food safety requirements.

(5) Section 34 (which relates to time limits for the commencement of prosecutions) of the Act shall apply in relation to offences under these Regulations as it applies to offences punishable under section 35(2) of the Act.

Revocations

22. The Regulations specified in Schedule 12 to these Regulations are revoked to the extent specified in Column 3 of that Schedule from the date these Regulations come into force.

Consequential amendments

23. The Food Premises (Registration) Regulations 1991^(a) shall be amended as follows -

- (a) for sub-paragraph (a) of regulation 3(2) there shall be substituted the following paragraph -

"(a) as a production holding or as a dairy establishment, in each case within the meaning, in relation to England and Wales, of the Dairy Products (Hygiene) Regulations 1994;"

- (b) sub-paragraph (b) of regulation 3(2) shall be deleted.
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NB No Page 31

^(a) S.I. 1991/2825

**SCHEDULE 1 Regulations 4(1)(a), (3)(a) and (7)
and 9(1)(a)**

**CONDITIONS FOR REGISTRATION OF PRODUCTION HOLDINGS
PART 1**

A. GENERAL CONDITIONS OF HYGIENE FOR PRODUCTION HOLDINGS

1. All animals shall be clean and well-kept. Individual cows in a herd shall be identifiable by an authorised officer.
2. Production holdings shall have the capability to isolate effectively from the rest of the herd any animals infected, or suspected of being infected with tuberculosis, brucellosis or any other disease communicable to humans through consumption of milk.
3. Animals of all species shall be kept away from premises and sites where milk is stored, handled or cooled.
4. Pigs and poultry shall not be housed in premises where animals are housed or milked.
5. Access to the premises in which animals are housed or milked or any premises on the production holding in which milk is handled, cooled or stored shall be kept free from accumulations of dung, droppings or other offensive matter. Dung channels and droppings on the production holding shall be cleared regularly as necessary.
6. Adequate measures shall be taken to control insects, rodents and other vermin on the production holding.
7. Store-rooms and cleaning-rooms and the equipment in such rooms shall be kept clean, tidy and in good condition.
8. The holding bay for ewes and goats, where it exists, shall be kept in a clean and tidy condition.

B. GENERAL CONDITIONS OF HYGIENE APPLICABLE TO STAFF

1. The highest standards of cleanliness shall be required at all times of staff and persons engaged in milking and handling of raw milk. In particular they shall:
 - (a) wear suitable clean working clothes;
 - (b) wash their hands immediately before commencing milking or handling of raw milk and shall keep them clean, as far as practicable, throughout the milking or handling operation; and
 - (c) keep any wounds to the skin covered with a waterproof dressing.
2. The occupier shall take all requisite measures to prevent persons liable to contaminate raw milk from handling it, unless there is evidence that such persons can do so without risk of contamination.
3. Before the recruitment of any person for milking or handling raw milk, such person shall be required to show that there is no medical impediment to such employment.

PART II CONDITIONS FOR HOUSING OF ANIMALS

1. The premises housing milking animals shall be designed, sited, constructed, maintained and managed so as to ensure good conditions of housing, hygiene, cleanliness and health of the animals.
2. The stalls or lying areas shall be kept dry; if necessary by the use of bedding which is regularly changed.
3. Washing, cleaning and disinfection of the premises housing milking animals or any outhouses attached to such premises shall be carried out in such a way so as to ensure that it does not have an adverse effect on the milk. Any disinfectants used shall be acceptable to the authorised officer.
4. Where one or more rams or male goats are used for breeding, separate accommodation shall be provided for them so as to avoid contamination with odours.

PART III
CONDITIONS FOR MILKING AND THE HANDLING, COOLING AND STORAGE OF
RAW MILK ON THE PRODUCTION HOLDING

A. STRUCTURE OF THE PREMISES

1. Premises in which animals are milked or in which raw milk is handled, cooled or stored shall -
 - (a) be designed, sited, constructed, maintained and managed in such a way as to ensure satisfactory hygiene conditions for milking operations and for the handling, cooling and storing of milk and shall provide adequate separation from all sources of contamination, including lavatories and dung heaps;
 - (b) have walls and floorings in areas liable to soiling or infection, and fittings and equipment, which are easy to clean and disinfect;
 - (c) have suitable means of waste disposal, including flooring which allows liquids to drain away;
 - (d) have adequate ventilation and lighting;
 - (e) have a sufficient supply of potable water for use in milking operations, and for the cleaning of equipment and utensils intended to come into contact with milk;
 - (f) have suitable facilities near the place of milking to enable milkers and persons handling milk to wash their hands and arms;
 - (g) in the case of production holdings where milk-producing animals are kept untethered in the open, have a milking parlour, or a milking area for the milking of animals, which is adequately separated from any housing area; and
 - (h) in the case of milk storage premises, have suitable refrigeration equipment, adequately protected against vermin and adequately separated from any premises where any animals are housed or milked.



2. If a processing or treatment establishment is attached to a production holding for ewes and goats, there shall be no direct communication between premises where the ewes and goats are housed or milked, and the processing or treatment establishment.

B. EQUIPMENT

1. Equipment and instruments or their surfaces which are intended to come into contact with milk in premises in which animals are milked or in which milk is handled, cooled or stored shall be made of smooth material which is easy to clean and disinfect, which resists corrosion and which will not transfer substances to milk in such quantities as to endanger human health, impair the composition of milk or adversely affect its organoleptic characteristics.
2. Equipment, utensils and all their components used for milking shall be kept clean and maintained in good physical condition at all times.
3. After use, any utensils used for milking, mechanical milking equipment and containers which come into contact with milk shall be cleaned and disinfected and rinsed with potable water.
4. Bulk milk tanks when empty shall be left with an open plug hole or, where appropriate, an open outlet valve.
5. Where milking is done by hand, the pails containing the milk shall be covered and brought as quickly as possible to the milk storage premises.

C. OPEN-AIR MILKING AND MOVEABLE MILKING BAILS

1. Where milking is done in the open, the ground where it takes place shall be clean.
2. Where a moveable milking bail is used, it shall -
 - (a) have a sufficient supply of potable water for use in milking operations and for the cleaning of equipment, utensils and all their components intended to come into contact with milk;
 - (b) have fittings and equipment which are easy to wash, clean and disinfect;

- (c) be sited on ground which is free of any accumulation of excreta or other waste matter;
- (d) provide adequate protection for the milk during the whole period in which the bail is in use;
- (e) be so constructed and finished as to permit the interior surfaces to be kept clean.

D. FEEDINGSTUFFS

1. Feedstuffs shall not be stored on a production holding where they can have an adverse effect on milk.

PART IV CONDITIONS FOR MILKING AND FILTERING OPERATIONS

1. Any work including feeding of animals, that might have an adverse effect on the milk shall not be carried out immediately before or during the milking.
2. Before the milking is started the teats, udder, flank, hindquarters and adjacent parts of the abdomen of the animal shall be clean.
3. At the start of the milking of an individual animal, the milker shall inspect the appearance of the milk. If any physical abnormality in the milk is detected, milk from that animal shall not be allowed to leave the production holding, nor shall it be used for human consumption on that production holding.
4. Animals with clinical udder diseases shall be milked last, or by a separate machine, or handstripped. Milk from such animals shall not be allowed to leave the production holding, nor shall it be used for human consumption on that production holding.
5. Teat dips or sprays for lactating animals shall only be used immediately after milking, unless otherwise permitted by an authorised officer. The components of the teat dips and sprays used shall be those acceptable to the authorised officer.

6. Where the milk is filtered, the filter used shall, depending on the type, be changed or cleansed before its capacity for absorption is exhausted. In any case, the filter shall be changed or cleansed before each milking. Filtering cloths shall not be used for cows' milk.

**SCHEDULE 2 Regulations 3(7), 6(1)(a), (3)(a),
(7), and (8), 9(1)(a), 15(1)(a) and
20(a), (b) and (e)**

CONDITIONS FOR APPROVAL OF DAIRY ESTABLISHMENTS

PART I

GENERAL CONDITIONS OF HYGIENE FOR DAIRY ESTABLISHMENTS

1. Dairy establishments shall have the following:
 - (a) facilities for the hygienic handling and protection of raw materials and of non-packaged or non-wrapped dairy products during loading and unloading;
 - (b) appropriate arrangements for protection against pests;
 - (c) instruments and working equipment intended to come into direct contact with raw materials and dairy products which are made of corrosion-resistant material and which are easy to clean and disinfect;
 - (d) special watertight, non-corrodible containers in which to put raw materials or dairy products not intended for human consumption. Where such raw materials or dairy products are removed through conduits, these shall be constructed and installed in such a way so as to avoid any risk of contamination of other raw materials or dairy products;
 - (e) appropriate facilities for the cleaning and disinfecting of equipment and instruments;
 - (f) an adequate waste water disposal system which is hygienic;
 - (g) a supply of potable water only. However a supply of non-potable water is also permitted provided that it is intended only for the cooling of equipment, steam production, fire-fighting and refrigeration equipment, and provided further that the

pipes installed for this purpose preclude the use of this water for other purposes and present no direct or indirect risk of contamination of the dairy products.

Non-potable water pipes shall be clearly distinguished from those used for potable water,

- (h) an appropriate number of changing rooms with smooth, waterproof, washable walls and floors and within the room or in its immediate vicinity, wash basins with non hand-operable taps, hygienic hand-drying facilities and flush lavatories. The lavatories shall not open directly on to the work rooms;
- (i) a lockable room or a secure place for the storage of detergents, disinfectants and similar substances;
- (j) a room or cupboard for storing cleaning and maintenance material;
- (k) adequate facilities for cleaning and disinfecting tanks used for transporting dairy products. However such facilities shall not be compulsory if alternative facilities which are acceptable to the approving authority are available to the dairy establishment for such purpose;
- (l) rooms with adequate capacity for storing raw materials and dairy products.

2.-(1) Dairy establishments shall have working areas of sufficient size for work to be carried out under adequate hygienic conditions; their design and layout shall be such as to preclude contamination of the raw materials and the dairy products.

(2) The production of heat-treated milk or the manufacture of milk-based products which might pose a risk of contamination to other dairy products shall be carried out in a clearly separated working area.

(3) In areas where raw materials are handled and dairy products are manufactured, the areas shall have the following:

- (a) solid, waterproof flooring which is easy to clean and disinfect and which allows water to drain away, and equipment to remove water;

- (b) walls which have smooth surfaces and are easy to clean, are durable and impermeable and which are covered with a light-coloured coating;
- (c) ceilings or roof linings which are easy to clean in those areas where exposed or non-packaged raw materials or dairy products are handled;
- (d) doors made of non-corrodible materials which are easy to clean;
- (e) adequate ventilation and, where necessary, good steam and water-vapour extraction facilities;
- (f) adequate natural or artificial lighting;
- (g) an adequate number of facilities with hot and cold running water, or water pre-mixed to a suitable temperature, for cleaning and disinfecting hands; taps in work rooms and lavatories for cleaning and disinfecting hands which shall be non hand-operable; these facilities shall be provided with cleaning and disinfecting materials and a hygienic means of drying hands;
- (h) facilities for cleaning tools, equipment and installations.

3.-(1) Subject to sub-paragraphs (2) and (3) of this paragraph, the rooms where raw materials and dairy products are stored shall comply with the requirements specified in paragraph 2(3)(a) to (f) above.

(2) Raw materials and dairy products may be stored in rooms notwithstanding failure to comply with all or any of the requirements of paragraph 2(3)(a) to (f) above provided that -

- (a) in the case of chilling and refrigeration rooms they have a floor which is easy to clean and disinfect and which allows water to drain away; or
- (b) in the case of freezing and deep-freezing rooms they have a floor which is waterproof, rotproof and easy to clean; and
- (c) in the cases referred to in sub-paragraphs (a) and (b) above, the rooms have a sufficiently powerful refrigeration plant to keep raw materials and dairy products at the temperatures specified by these Regulations.

(3) In freezing and deep-freezing rooms referred to in sub-paragraph (2)(b) of this paragraph, the use of wooden walls shall be permitted provided they were built before 1st January 1993.

PART II

SPECIAL CONDITIONS FOR APPROVAL

A. SPECIAL CONDITIONS FOR APPROVAL OF TREATMENT AND PROCESSING ESTABLISHMENTS

1. In addition to the general requirements laid down in Part I of this Schedule, treatment establishments and processing establishments shall have the requirements set out below in this Part.
2. The establishment shall possess equipment for the mechanical filling and proper automatic sealing of containers (excluding churns, tanks and bulk packaging of more than 4 litres) which are to be used for packaging heat-treated drinking milk and liquid milk-based products, if such operations are carried out there. **However in the case of limited production, alternative non-automatic sealing methods may be used with the prior authorisation of the approving authority provided that such methods carry equal assurance with regard to hygiene*.**
3. The establishment shall possess equipment for the cooling and cold storage of heat-treated milk and liquid milk-based products. Where raw milk is stored, purified or standardised at an establishment, that establishment shall also possess equipment for the cooling and cold storage of raw milk. Cold stores shall be equipped with correctly calibrated temperature-measuring apparatus.
4. The establishment shall possess -
 - (a) in the case of dairy products wrapped in disposable containers, **an area for the storage of such containers and for the storage of raw materials intended for their manufacture; and**
 - (b) in the case of dairy products wrapped in re-usable containers, **a special area for their storage, and equipment designed to clean and disinfect them mechanically.**

5. The establishment shall possess containers for storing raw milk and, if appropriate, standardisation equipment and containers for storing standardised milk.
6. The establishment shall possess centrifuges or any other suitable means for physically purifying milk, if appropriate.

7.-(1) Subject to sub-paragraph (2) below, a treatment establishment shall possess heat-treatment equipment, approved or authorised by the approving authority for the treatment of dairy products, fitted with:

- (a) in the case of a continuous heat treatment system:
 - (i) an automatic temperature control;
 - (ii) a recording thermometer;
 - (iii) an automatic safety device preventing insufficient heating;
 - (iv) an adequate safety system preventing the mixture of heat-treated drinking milk with milk which has not been fully heat-treated, and
 - (v) **an automatic recording device*** which records the operation of the safety system referred to in sub-paragraph (iv) above;
- (b) in the case of any other heat treatment system, at least a recording thermometer.

(2) **A treatment establishment may have equipment different to those specified in paragraph (1) of this paragraph provided that an equivalent performance may be achieved with the same hygiene guarantees and the approving authority has authorised the use of such different equipment.**

8. **A processing establishment shall possess equipment for heating, thermisation or heat-treatment if such operations are carried out in that establishment which meets hygiene requirements and is approved or authorised by the approving authority.***

9. The establishment shall possess equipment for the cooling, wrapping and storage of frozen milk-based products, if such operations are carried out at that establishment.

10. The establishment shall possess equipment for drying and wrapping powdered milk products, if such operations are carried out at that establishment.

B. SPECIAL CONDITIONS FOR APPROVAL OF A COLLECTION CENTRE

1. In addition to the general requirements laid down in Part I of this Schedule, a collection centre shall have -
 - (a) cooling equipment or appropriate means for cooling milk and, if milk is stored at that collection centre, a cold-storage installation;
 - (b) if milk is purified at that collection centre, centrifuges or any other apparatus suitable for the physical purification of milk.

C. SPECIAL CONDITIONS FOR APPROVAL OF A STANDARDISATION CENTRE

1. In addition to the general requirements laid down in Part I of this Schedule, a standardisation centre shall have -
 - (a) containers for the cold storage of raw milk;
 - (b) standardisation equipment and containers for the storage of standardised milk;
 - (c) centrifuges or any other apparatus suitable for the physical purification of milk.

PART III
GENERAL CONDITIONS OF HYGIENE

A. GENERAL CONDITIONS OF HYGIENE APPLICABLE TO DAIRY ESTABLISHMENTS, INSTRUMENTS AND EQUIPMENT

1. Rodents, insects and any other vermin shall be systematically destroyed in the dairy establishment and animals of any species shall be prevented from entering rooms in which dairy products are manufactured or stored.
2. Instruments and equipment used for working on raw materials and dairy products, floors, ceilings or roof linings, walls and partitions shall be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination to raw materials or dairy products.
3. Rodenticides, insecticides, disinfectants and any other potentially toxic substance shall be stored in lockable rooms or a secure place and used in such a way that they do not have an adverse effect on machinery, equipment, instruments, raw materials or dairy products kept in the dairy establishment.
4. Working areas, instruments and working equipment shall be used only for work on dairy products in accordance with these Regulations. However, with the prior authorisation of the approving authority, they may be used at the same time or at other times for work on other foodstuffs fit for human consumption, **or other milk-based products intended for a use other than human consumption** [provided that adequate precautions are taken so as to ensure that] **they do not contaminate the dairy products** [intended for human consumption] **for which agreement has been given***.
5. Potable water shall be used for all purposes save as specified in paragraph 1(g) of Part I of this Schedule.
6. Subject to paragraph (7) below, equipment, containers and installations which come into contact with dairy products or perishable raw materials used during production shall be cleaned and if necessary disinfected **according to a cleaning programme based on risk analysis principles**.

7. Equipment, containers, instruments and installations which come into contact with microbiologically stable dairy products and the rooms in which they are stored shall be cleaned and disinfected according to a cleaning programme based on risk analysis principles drawn up by the occupier of the dairy establishment.
8. As soon as possible after unloading or after each series of journeys where there is only a very short space of time between unloading and the following loading, but in any event at least once each working day, any container or tank used for transporting raw milk shall be cleaned and disinfected before re-use.
9. The treatment establishment shall in principle be cleaned **according to a cleaning programme based on risk analysis principles**. The dairy establishment shall take appropriate measures to avoid cross-contamination of dairy products in accordance with the cleaning programme specified in paragraph 7 above.
10. Where appropriate, rooms intended for production processes shall be divided into wet and dry areas, each having its own operating conditions.
11. Disinfectants and similar substances used shall be those acceptable to the approving authority and shall be used in such a way that they do not have any adverse effects on the machinery, equipment, raw materials and dairy products kept at the dairy establishment. They shall be in clearly identifiable containers bearing labels with instructions for their use and their use shall be followed by thorough rinsing of such instruments and working equipment with potable water, except in cases where the disinfectant or similar substance is specifically designed not to be rinsed after application.
12. Where a dairy establishment produces foodstuffs containing dairy products, together with other ingredients which have not undergone heat-treatment, or other treatment having an equivalent effect, such dairy products and ingredients shall be stored separately to prevent cross-contamination.

B. GENERAL CONDITIONS OF HYGIENE APPLICABLE TO STAFF

1. The occupier of a dairy establishment shall only employ persons in such an establishment to work directly with and handle raw materials or dairy products if those persons have proved to the occupier's satisfaction by means of a medical certificate, on recruitment, that there is no medical impediment to their

employment in that capacity. This requirement shall not apply to any persons already working in such a capacity before the date on which these Regulations come into force.

2. Persons working directly with and handling raw materials or dairy products shall maintain the highest standards of personal cleanliness at all times. In particular they shall:-
 - (a) wear suitable, clean, working clothes and headgear which completely encloses their hair;
 - (b) not smoke, spit, eat or drink in rooms where raw materials and dairy products are handled or stored;
 - (c) wash their hands at least each time work is resumed and whenever contamination of their hands has occurred; and
 - (d) cover wounds to the skin with a suitable waterproof dressing.
3. The occupier shall take all necessary measures to prevent persons liable to contaminate raw materials and dairy products from handling them until the occupier has adequate evidence that such persons can do so without risk of contamination.

REQUIREMENTS FOR RAW MILK

PART 1

ANIMAL HEALTH STANDARDS

1. Raw milk shall come from animals on a registered production holding and such animals shall -
- (a) not show any symptoms of infectious diseases communicable to human beings through milk;
 - (b) not give the milk any abnormal organoleptic characteristics;
 - (c) have a general state of health which is not impaired by any visible disorder and which are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognisable inflammation of the udder;
 - (d) not show any udder wound likely to affect their milk;
 - (e) not have had substances within the meaning of Council Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action^(a), as amended^(b), and Council Directive 88/146/EEC prohibiting the use in livestock farming of certain substances having a hormonal action^(c), administered illegally;
 - (f) not have been treated with substances dangerous or likely to be dangerous to human health that are transmissible to milk unless any withdrawal period which may apply to it has been observed.
2. In addition to the requirements specified in paragraph (1) above -

^(a) OJ No. L222, 7.8.81, p.32.

^(b) Council Directive 85/358/EEC (OJ No. L191, 23.7.85, p.46), to which there are amendments not relevant to these Regulations.

^(c) OJ No. L70, 16.3.1988, p.16.



- (a) raw cows' milk and raw buffaloes' milk shall come from animals belonging to a herd which is officially tuberculosis-free and either brucellosis-free or officially brucellosis-free;
- (b) raw cows' milk shall come from animals yielding at least two litres of milk per day;
- (c) raw ewes' milk and raw goats' milk shall come from animals belonging to a production holding which is either brucellosis-free or officially brucellosis-free (*Brucella melitensis*) within the meaning of Article 2(4) and (5) of Council Directive 91/68/EEC^(a).

3. When different animal species are kept together on a production holding, each such species shall satisfy the health conditions which would be required if it were alone.

PART II

RAW MILK STANDARDS

1. Raw milk at the time of its collection from a registered production holding or at the time of its acceptance at a treatment or processing establishment shall not contain:-

- (a) any added water,
- (b) antibiotic residues in excess of the levels authorised in Annexes I and III of Council Regulation (EEC) No. 2377/90 on Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin^(b), as amended^(c), nor contain any combination of such substances in excess of a value to be fixed in accordance with that Council Regulation; and
- (c) residues of substances having a pharmacological or hormonal action, or pesticides, detergents or other substances which are harmful or which might alter the organoleptic characteristics of dairy products or make their consumption dangerous, or harmful to human health insofar as those residues exceed permitted tolerance limits.

^(a) OJ No. L46, 19.2.91, p.19.

^(b) OJ No. L224, 18.8.1990, p.1.

^(c) Relevant amending instruments are Commission Regulation (EEC) No. 675/92 (OJ No. L73, 19.3.1992, p.8), Commission Regulation (EEC) No. 3093/92 (OJ No. L311, 28.10.92, p.18), Commission Regulation (EEC) No. 895/93 (OJ No. L93, 17.4.1993, p.10) and Commission Regulation (EEC) No. 3426/93 (OJ No. L312, 15.12.93, p.15).

2. In addition to the requirements specified in paragraph (1) above -

- (a) raw cows' milk intended for the production of heat-treated drinking milk, fermented milk, junket, jellied milk, flavoured milk or cream shall meet the following standards:

Plate count at 30°C (per ml)	≤ 100,000
Somatic cell count (per ml)	≤ 400,000

- (b) raw cows' milk intended for the manufacture of any dairy products other than those referred to in sub-paragraph (a) above shall meet the following standards:

	From 1.1.94	From 1.1.98
Plate count at 30°C (per ml)	≤ 400,000	≤ 100,000
Somatic cell count (per ml)	≤ 500,000	≤ 400,000

- (c) raw cows' milk intended for [export to another member State for consumption as raw drinking milk or for] the production of any raw milk-based product which will not undergo any heat treatment during its manufacture shall meet the following standards:

Plate count at 30°C (per ml)	≤ 100,000
Somatic cell count (per ml)	≤ 400,000
<u>Staphylococcus aureus</u> (per ml)	n = 5, c = 2, m = 500, M = 2000

- (d) raw ewes' or goats' milk intended for the production of heat-treated drinking milk or for the manufacture of heat-treated milk-based products shall meet the following standard:

Plate count at 30°C (per ml)	≤ 1,000,000
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- (e) raw ewes' or goats' milk intended for the manufacture of any milk-based product which will not undergo any heat treatment during its manufacture shall meet the following standards:

Plate count at 30°C (per ml)	≤ 500,000
<u>Staphylococcus aureus</u> (per ml)	n = 5, c = 2, m = 500, M = 2000

- (f) subject to the exception of sub-paragraph (g) below, raw buffaloes' milk intended for the manufacture of any dairy product, shall meet the following standards:

Plate count at 30°C (per ml)	≤ 1,000,000
Somatic cell count (per ml)	≤ 500,000

- (g) raw buffaloes' milk intended for the production of any raw milk-based product which will not undergo any heat treatment during its manufacture shall meet the following standards:

Plate count at 30°C (per ml)	≤ 500,000
Somatic cell count (per ml)	≤ 400,000
<u>Staphylococcus aureus</u> (per ml)	n = 5, c = 2, m = 500, M = 2000

3. For the purposes of the tables set out in paragraph 2 above, the symbols referred to shall have the following meanings -

n = number of sample units comprising the sample;

c = number of sample units where the bacterial count may be between 'm' and 'M', the sample being considered acceptable if the bacterial count of the other sample units is 'm' or less;

m = threshold value for the number of bacteria, the result is considered satisfactory if the number of bacteria in all sample units does not exceed 'm';

M = maximum value for the number of bacteria, the result is considered unsatisfactory if the number of bacteria in one or more sample units is 'M' or more.

4. The occupier shall ensure that -

- (a) compliance with the standards referred to in paragraph 2 above is checked by random sampling either on collection at the production holding or on acceptance of the raw milk at the treatment establishment or processing establishment;
- (b) the plate count at 30°C is calculated on the basis of a geometric average over a period of two months, with at least two samples a month;

- (c) the somatic cell count is calculated on the basis of a geometric average over a period of three months, with at least one sample a month.

PART III

CHECKS FOR ADDED WATER IN RAW MILK

1. Raw milk shall be subjected to regular checks and sampling to ascertain if water is being added to such milk.
2. Such checks shall include regular checks on the freezing point of raw milk supplied by each production holding and shall be carried out in accordance with the following procedure:-
 - (a) raw milk supplied by each production holding shall be subjected regularly to random sampling;
 - (b) where the raw milk of a single production holding is delivered directly to a processing establishment or a treatment establishment, the samples for checking shall be taken -
 - (i) when the raw milk is collected from the holding for transport to such establishment, provided that adequate precautions are taken to prevent any fraud during such transport of the raw milk; or
 - (ii) before unloading the raw milk at the processing establishment or treatment establishment, when the delivery there is made by the occupier of the production holding;
 - (c) where raw milk delivered to a processing establishment or treatment establishment comprises of a mixture of such milk obtained from more than one production holding, the samples for checking shall be taken -
 - (i) in accordance with sub-paragraph (b) above, or
 - (ii) when the raw milk enters the dairy establishment, provided that spot checks are also carried out at the production holdings from which the raw milk was obtained; and

- (iii) if the results of any of the checks on a sample of such mixture of raw milk lead to a suspicion that water has been added to such milk, samples for checking shall be taken from all the production holdings from which the raw milk was obtained.

REQUIREMENTS FOR DRINKING MILK

PART I

RAW MILK FOR DRINKING

1. Drinking milk which is raw milk shall meet the following standards:

Plate count at 30°C (per ml)	≤ 20,000
Coliforms (per ml)	≤ 100

2. Drinking milk which is raw cows' milk which is intended for export to another member State shall meet the following standards after wrapping:

Plate count at 30°C (per ml)	≤ 50,000 calculated on the basis of a geometric average over a period of two months, with at least two samples a month.
<u>Staphylococcus aureus</u> (per ml)	n = 5, c = 2, m = 100, M = 500
<u>Salmonella</u> spp	Absence in 25ml n = 5, c = 0

In addition, pathogenic micro-organisms and their toxins shall not be present in quantities such as to affect the health of a consumer.

3. Where raw milk has not passed through a milk collection centre, it shall be transferred from one tank to another in hygienic conditions.

PART II

RAW MILK FOR HEAT TREATMENT

1. (1) Raw milk, at the time of its acceptance at a treatment establishment, unless treated within 4 hours of acceptance, shall be cooled to a temperature not exceeding 6°C and maintained at that temperature until heat treated;
- (2) Where raw cows' milk is not treated within 36 hours of acceptance at a treatment establishment, a further test shall be carried out on such milk before it is heat-treated. If it is found by means of a direct or indirect method that the plate count of that milk at 30°C exceeds 300,000 per ml, then such milk shall not be used for the production of heat-treated drinking milk;
- (3) In the case of buffaloes', goats' or ewes' milk, random sampling checks shall be carried out on such milk before it is heat-treated to ensure that it does not exceed a plate count at 30°C of 1,000,000 per ml.

PART III

HEAT-TREATED DRINKING MILK

1. Heat-treated drinking milk shall not contain -
 - (a) any pharmacologically active substance in a quantity higher than the limits laid down in Annexes I and III of Council Regulation (EEC) No. 2377/90^(a) as amended^(b) nor contain any combination of such substances in excess of a value to be fixed in accordance with that Council Regulation; or
 - (b) any added water.
2. In addition to complying with paragraph 1 above, pasteurised milk shall -
 - (a) have been obtained by means of a heat-treatment involving a high temperature for a short time (at least 71.7°C for 15 seconds or any equivalent combination) or a pasteurisation process using different time and temperature combinations to obtain an equivalent effect;

^(a) OJ No. L224, 18.8.90, p.1.

^(b) Relevant amending instruments are Commission Regulation (EEC) No. 675/92 (OJ No. L73, 19.3.92, p.8) and Commission Regulation (EEC) No. 895/93 (OJ No. L93, 17.4.93, p10).

- (b) show a negative reaction to the phosphatase test as specified in Schedule 11 and, a positive reaction to the peroxidase test as specified in that Schedule or, in the case of high temperature pasteurised milk, show a negative reaction to both tests; and
- (c) meet the following microbiological standards in any random sampling checks carried out in the treatment establishment:

Pathogenic micro-organisms	Absence in 25g $n = 5, c = 0$
Coliforms (per ml)	$n = 5, c = 1, m = 0, M = 5$
Plate count at 21°C (per ml)	$n = 5, c = 1, m = 5 \times 10^4, M = 5 \times 10^5$
after incubation at 6°C for five days.	

3. In addition to complying with paragraph 1 above, sterilised and UHT milk shall, after it has spent 15 days in a closed container at a temperature of 30°C or, seven days in a closed container at a temperature of 55°C, meet the following standards -
- (a) be organoleptically normal;
- (b) not show any sign of deterioration;
- (c) have a plate count at 30°C ≤ 100 per ml.
4. In addition to complying with paragraphs 1 and 3 above, sterilised milk shall be heated and sterilised either in a hermetically sealed wrapping or container, the seal of which shall remain intact during such heat-treatment, or by use of the continuous flow process.
5. In addition to complying with paragraphs 1 and 3 above, UHT milk shall -
- (a) be obtained by applying heat to a continuous flow of raw milk entailing the application of a high temperature for a short time (not less than 135°C for not less than a second) so that all residual spoilage micro-organisms and their spores are destroyed, but that the chemical, physical and organoleptic changes to the milk are minimal;
- (b) be placed immediately after completion of the heat-treatment process into aseptic opaque containers, or containers made opaque by the packaging; and

- (c) in cases where it is obtained from a heat-treatment process which employs the direct contact of milk and steam, the steam shall be obtained from potable water. Such steam shall not leave deposits of foreign matter in the milk or affect it adversely. The use of this process shall be so as not to cause any change in the water content of the treated milk.

6. Heat-treated drinking milk may be produced from raw milk which has undergone thermisation or an initial heat-treatment [in that] or another establishment provided that -

- (a) such practice is brought to the attention of the approving authority;
- (b) the initial ^{thermisation or} heat-treatment process shall have had a time-temperature combination which is lower than or equivalent to the pasteurisation process specified in paragraph (2) above; and
- (c) milk which has undergone the initial ^{thermisation or} heat-treatment shall have shown a positive reaction to the peroxidase test as specified in Schedule 11, before the second heat treatment.

7. Pasteurised milk may be produced from raw milk which has undergone only initial thermisation in accordance with the same conditions specified in paragraph 6 above*.

8. The definition of the symbols specified in paragraph 3 of Part II of Schedule 3 shall apply for the purposes of the tables in paragraph 1 of Part I, and paragraph 2 of Part III of this Schedule.

**REQUIREMENTS FOR MILK USED FOR THE MANUFACTURE OF
MILK-BASED PRODUCTS**

**PART I
RAW MILK**

1. Subject to paragraph 2 below, the occupier of the processing establishment shall take all necessary steps to ensure that the raw milk is treated, or that the production of milk-based products using raw milk shall commence:

- (a) as soon as possible after acceptance [of such raw milk] at the processing establishment where the raw milk has not been refrigerated;
- (b) within 36 hours of such acceptance of the raw milk, provided that the raw milk is kept at a temperature not exceeding 6°C prior to such commencement; or
- (c) within 48 hours of such acceptance [of the raw milk,] if the raw milk is kept at a temperature of 4°C or lower;

2. For technological reasons relating to the manufacture of certain milk-based products, the times and temperatures referred to in paragraph 1 above may be exceeded with the prior authorisation of the approving authority.

**PART II
THERMISED MILK**

1. Thermised milk shall:

- (a) be obtained from raw milk and where thermisation of such raw milk has not commenced within 36 hours of acceptance by the processing establishment, it shall have a plate count at 30°C prior to thermisation which does not exceed 300,000 per ml in the case of cows' milk and 1,000,000 per ml in the case of buffaloes', goats' or ewes' milk;

- (b) be obtained by the heating of raw milk for at least 15 seconds at a temperature between 57°C and 68°C such that after completion of the heating process the milk shows a positive reaction to the phosphatase test as specified in Schedule 11; and
- (c) if it is used to produce pasteurised, UHT or sterilised milk intended for the manufacture of milk-based products, have a plate count at 30°C equal to or less than 100,000 per ml before heat treatment.

PART III

PASTEURISED MILK

1. **Pasteurised milk shall:**

- (a) be obtained by means of a heat treatment involving a high temperature for a short time (at least 71.7°C for 15 seconds, or any equivalent combination) or a pasteurisation process using different time and temperature combinations to obtain an equivalent effect; and
- (b) show a negative reaction to the phosphatase test as specified in Schedule 11 and a positive reaction to the peroxidase test as specified in that Schedule or, in the case of high temperature pasteurised milk, show a negative reaction to both those tests.

PART IV

UHT MILK

1. UHT milk shall be obtained by applying heat to a continuous flow of milk entailing the application of a high temperature for a short time (not less than + 135°C for not less than a second) so that all residual spoilage micro-organisms and their spores are destroyed but that the chemical, physical and organoleptic changes to the milk are minimal.

REQUIREMENTS FOR MILK-BASED PRODUCTS

PART I

MICROBIOLOGICAL CRITERIA

1. Milk-based products shall not contain pathogenic micro-organisms and toxins from pathogenic micro-organisms in such quantity as to affect the health of the ultimate consumer.
2. Sterilised or ultra heat-treated milk-based products which are intended for conservation at room temperature shall meet the following standards after incubation at 30°C for 15 days -
 - (a) have a plate count at 30°C $\leq$ 100 per ml;
 - (b) be organoleptically normal.
3. Subject to paragraph 4 below, milk-based products shall meet the standards referred to in the tables below -

A.

	Product	Type of Micro-organism	Standard
(i)	Cheese, other than hard cheese	<u>Listeria monocytogenes</u>	Absence in 25g where n = 5, c = 0
(ii)	Milk-based products, other than cheese covered by (i) above	<u>Listeria monocytogenes</u>	Absence in 1g
(iii)	Milk powder	<u>Salmonella</u> spp	Absence in 25g where n = 10, c = 0
(iv)	Milk products, other than milk powder	<u>Salmonella</u> spp	Absence in 25g where n = 5, c = 0

The sample of 25g referred to in paragraph (i) of table A above shall consist of 5 specimens of 5g taken from different parts of the same product.

B.

Product	Type of Micro-organism	Standard (ml, g)
Cheese made from raw milk or from thermised milk	<u>Staphylococcus aureus</u>	n = 5, c = 2, m = 100, M = 10,000
	<u>Escherichia coli</u>	n = 5, c = 2, m = 10,000, M = 100,000
Soft cheese made from heat-treated milk	<u>Staphylococcus aureus</u>	} n = 5, c = 2
	<u>Escherichia coli</u>	} m = 100, M = 1,000
Fresh Cheese	<u>Staphylococcus aureus</u>	}
Powdered milk	<u>Staphylococcus aureus</u>	} n = 5, c = 2
		} m = 10, M = 100
Frozen milk-based products including ice-cream	<u>Staphylococcus aureus</u>	}

4. The symbols specified in paragraph 3 of Part II of Schedule 3 shall apply for the purposes of the tables in paragraph 3 of Part I and paragraph 3 of Part II of this Schedule.
5. Testing of the milk-based products referred to in table A of paragraph 3 above shall not be compulsory for sterilised milk, preserved milk-based products and milk-based products where the heat-treatment was applied after wrapping or packaging.
6. Sampling programmes shall be drawn up by the occupier of the dairy establishment in the light of the nature of the dairy products and the principles of risk analysis.
7. In all cases where the standards in table A of paragraph 3 above are exceeded, the dairy products shall be excluded from human consumption and withdrawn from the market.
8. In all cases where the standards in table B of paragraph 3 above are exceeded, there shall be a review of the implementation of the methods for monitoring and checking critical points applied in the processing establishment. The occupier of the processing establishment shall inform the approving authority of the corrective procedures included in the production monitoring system to prevent any repetition of the occurrence.
9. Wherever the standard M in table B of paragraph 3 above is exceeded in the case of cheese made from raw milk, thermised milk or soft cheese, either -

- (a) testing shall be carried out for the possible presence of toxins in such products, or

- (b) strains of enterotoxigenic Staphylococcus aureus or strains of Escherichia coli that are presumed to be pathogenic shall be identified by a method determined in accordance with Article 31 of Council Directive 92/46, as specified in paragraph 2 of Chapter II of Annex C to that Directive.

10. If toxins are found or the strains referred to in paragraph 9 above are identified, then all the batches [of such cheese] involved shall be withdrawn from the market. In this case the occupier shall inform the approving authority of such findings, of the action taken to withdraw the batches in question and the corrective procedures introduced into the production monitoring system to prevent any repetition of the occurrence.

PART II PASTEURISED CREAM

1. Pasteurised cream shall be heated -
 - (a) to a temperature not less than 63°C and retained at that temperature for not less than 30 minutes;
 - (b) to a temperature not less than 72°C and retained at that temperature for not less than 15 seconds; or
 - (c) to such other temperature for such other period of time as has equivalent effect to paragraphs (a) and (b) above in relation to the elimination of vegetative pathogenic organisms in the cream.
2. The cream shall be cooled as soon as practicable after pasteurisation.
3. Pasteurised cream shall meet the following standard -

Coliforms (per ml)	$n = 5, c = 2, m = 0, M = 5$
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PART III STERILISED CREAM

1. Sterilised cream shall be heated -

- (a) to a temperature not less than 108°C and retained at that temperature for not less than 45 minutes; or
 - (b) to such other temperature for such other period of time as has equivalent effect to paragraph (a) above in relation to the elimination of vegetative pathogenic organisms.
2. The cream shall be cooled as soon as practicable after sterilisation.
3. Sterilised cream shall meet the standard referred to in paragraph 2(a) of Part I of this Schedule.

PART IV

ULTRA HEAT-TREATED CREAM

1. Ultra heat-treated cream shall be heated -
 - (a) to a temperature not less than 140°C and retained at that temperature for at least 2 seconds; or
 - (b) to such other temperature for such other period of time as has equivalent effect to paragraph (a) above in relation to the elimination of vegetative pathogenic organisms.
2. The cream shall be cooled as soon as practicable after being ultra heat-treated.
3. Ultra heat-treated cream shall meet the standard referred to in paragraph 2(a) of Part I of this Schedule.

PART V

ICE-CREAM - PASTEURISED

- 1.-(1) For the purposes of this Schedule the expression "the mixture" shall mean any product which is capable of manufacture into ice-cream by freezing only.
- (2) Pasteurised ice-cream shall be obtained by the mixture being heated -

- (a) to a temperature of not less than 65.6°C and retained at that temperature for not less than 30 minutes;
- (b) to a temperature of not less than 71.1°C and retained at that temperature for not less than 10 minutes; or
- (c) to a temperature of not less than 79.4°C and retained at that temperature for not less than 15 seconds;

then reduced to a temperature of not more than 7.2°C within 1½ hours and kept at such temperature until the freezing process is begun.

(3) If the temperature of ice-cream has risen above - 2.2°C at any time since it was frozen it shall not be sold or offered for sale unless -

- (a) it has again been subjected to the treatment (if any) to which as a mixture it was required to be subjected under paragraph (2) above; and
- (b) after having again been frozen, it has been kept at a temperature not exceeding - 2.2°C.

PART VI

ICE-CREAM - STERILISED

1. Sterilised ice-cream shall be obtained by the mixture being heated to a temperature of not less than 148.9°C for at least 2 seconds.
2. After the mixture has been sterilised as specified in paragraph 1 above, it shall be reduced to a temperature of not more than 7.2°C within 1½ hours and shall be kept at such a temperature until the freezing process is begun.
3. Paragraph 2 above shall not apply to a mixture which has been sterilised in accordance with the paragraph 1 above if immediately after the mixture has been sterilised it is placed in sterile airtight containers under sterile conditions and the container remains unopened.
4. The requirements of paragraph 1(3) of Part V of this Schedule shall apply to sterilised ice-cream.

STORAGE REQUIREMENTS

1. Immediately after milking, raw milk shall be placed in a clean place which is suitably equipped so as to prevent the raw milk suffering from any adverse effects.
- 2.-(1) Where raw milk is:-
 - (a) collected daily from a production holding it shall, if not collected within two hours of milking, be cooled as soon as practicable after milking to a temperature of 8°C or lower and maintained at that temperature until collected; or
 - (b) not collected daily from a production holding it shall be cooled as soon as practicable after milking to a temperature of 6°C or lower and maintained at that temperature until collected;
- (2) For technological reasons relating to the manufacture of certain goats' or ewes' milk-based products, and provided the end products meet the microbiological criteria specified in Part I of Schedule 6, the temperatures referred to in paragraphs (1)(a) and (b) above may be exceeded with the prior authorisation of the approving authority.
3. Upon acceptance at a treatment establishment milk shall, unless heat-treated within four hours of acceptance, be cooled to a temperature of 6°C or lower, if not already at such temperature, and maintained at that temperature until heat-treated.
4. When the pasteurisation process is completed, pasteurised milk shall be cooled as soon as practicable to a temperature of 6°C or lower.
5. Subject to paragraph 7 below, any dairy product not intended to be stored at ambient temperature shall be cooled as quickly as possible to the temperature established by the manufacturer of that product as suitable to ensure its durability and thereafter stored at that temperature.
6. Where dairy products other than raw milk are stored under cooled conditions, their storage temperatures shall be registered and the cooling rate shall be such that the products reach the required temperature as quickly as possible.

7. The maximum temperature at which pasteurised milk may be stored until it leaves the treatment establishment shall be 6°C.

SCHEDULE 8 Regulations 11(1)(a), (b) and 20(d)
TRANSPORT REQUIREMENTS
PART I
TEMPERATURE

1. The temperature of raw milk during transport to a treatment or processing establishment shall not exceed 10°C, unless the milk has been collected within 2 hours of milking. However, for technological reasons relating to the manufacture of certain goats' or ewes' milk-based products and provided the end products meet the microbiological criteria specified in Part I of Schedule 6, such requirement as to temperature may be exceeded with the prior authorisation of the approving authority.
2.
 - (1) Subject to sub-paragraphs (2) and (3) below, the temperature of pasteurised milk during transportation in tanks or packed in small containers and in churns shall not exceed 6°C.
 - (2) Where pasteurised milk is intended for delivery to a retail business, the temperature of such milk during transportation shall not exceed 8°C.
 - (3) The requirements as to temperature specified in sub-paragraphs (1) and (2) above shall not apply for milk intended for doorstep delivery.
3. Any vehicle or container used for transporting raw or pasteurised milk shall be designed and equipped in such a way that the temperatures specified in paragraphs 1 and 2 above shall be maintained throughout the period of such transport.

PART II
HYGIENE

1. Any vehicle used for transporting heat-treated drinking milk and milk in small containers or in churns shall be so designed as to give the containers or churns adequate protection against all contamination and atmospheric influences. It shall be maintained in good condition and shall not be used to transport any animals of any species or any other product or object likely to cause the milk to deteriorate. Those parts of the vehicle intended to come into contact with small containers or churns shall be smooth and easy to wash, clean and disinfect.
2. Any tank, churn or other container used for transporting raw milk or pasteurised milk shall be designed so that -

- (a) any surface which may come into contact with the milk shall be made of a material which is easy to wash, clean and disinfect, resists corrosion, and does not transfer substances to the milk in such quantity as to endanger human health, impair the composition of the milk or adversely affect the organoleptic characteristics of the milk;
- (b) the milk can drain away completely;
- (c) if they are fitted with taps, these shall be easy to remove, dismantle, wash, clean and disinfect; and
- (d) except in the case of a container or tank designed solely for the transport of raw milk, any container or tank in which pasteurised milk is transported shall be hermetically sealed before and during transportation by means of a watertight sealing device.

3. As soon as possible after each journey, or after each series of journeys where there is only a very short space of time between unloading and the following loading, but in any event at least once each working day, any container or tank used to transport raw milk or pasteurised milk to a dairy establishment shall be washed, cleaned and disinfected after each use and as necessary before further use.

4. Any tank used to transport milk shall bear a clear indication that it may be used only for the transport of foodstuffs.

5. Any tank used to transport dairy products may not be used for the transport of other foodstuffs unless adequate measures are taken to prevent contamination or deterioration of those dairy products.

6. Dairy products shall be despatched in such a way that they are protected during transportation from anything liable to contaminate them or cause them to deteriorate. For this purpose account shall be taken of the duration of the journey, the means of transport employed and the weather conditions.

PART III

COMMERCIAL DOCUMENT

1. Heat-treated drinking milk and milk-based products shall be accompanied during transport by a commercial document bearing the following particulars -

- (a) the details required on the health mark, specified in paragraph 4 of Part II of Schedule 10;
- (b) an indication of the nature of the heat-treatment used to produce the heat-treated drinking milk or milk-based product;
- (c) in the case of heat-treated drinking milk referred to in paragraph 6 of Part III of Schedule 4, an indication of the initial heat-treatment; and
- (d) an indication enabling the identification of the approving authority responsible for supervising the dairy establishment of origin, if such information is not clear from the approval number.

SCHEDULE 9 Regulations 11(1)(c) and 20(a)
WRAPPING AND PACKAGING

The requirements of this Schedule shall apply without prejudice to Council Directive 89/109/EEC on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs^(a).

1. Wrapping and packaging shall be strong enough to protect the dairy products effectively.
2. The wrapping and packaging of dairy products shall take place under satisfactory hygienic conditions and in rooms provided for that purpose.
3. Notwithstanding paragraph (2) above, the manufacture and packaging of dairy products may take place in the same room if the following conditions are satisfied -
 - (a) the room shall be sufficiently large and equipped to ensure the hygiene of the operations;
 - (b) the wrapping and packaging shall have been brought to the treatment or processing establishment in a protective cover in which they were placed immediately after manufacture and which protects the wrapping or packaging from any damage during transport to the dairy establishment, and they shall have been stored there under hygienic conditions in a room intended for that purpose;
 - (c) the rooms for storing the packaging material shall be free from vermin and from amounts of dust which could constitute an unacceptable risk of contamination of the product and shall be separated from rooms containing substances which might contaminate the products. Packaging shall not be placed directly on the floor;
 - (d) packaging shall be assembled under hygienic conditions before being brought into the room, except in the case of the automatic assembly of packaging, provided that there is no risk of contamination of the products;
 - (e) packaging shall be brought into the room under hygienic conditions and used without delay. It shall not be handled by staff handling unwrapped products, if there is a risk of cross-contamination; and

^(a) OJ No. L40, 11.2.89, p.38 to which there are amendments not relevant to these Regulations.

- (f) immediately after packaging, the dairy products shall be placed in the rooms provided for storage.

4. Bottling or filling of containers with heat-treated milk or liquid milk-based products shall be carried out mechanically and the sealing of the containers shall be carried out automatically. **However in the case of limited production and provided that those methods provide equal assurances with regard to hygiene*, non-automatic sealing methods may be used with the prior authorisation of the approving authority.**

5. Wrapping or packaging may not be re-used for dairy products, except where the containers are of a type which may be re-used after thorough cleaning and disinfecting.

6. Sealing shall be carried out in the treatment or processing establishment in which the **last heat-treatment of drinking milk or liquid milk-based products has been carried out**, immediately after filling, by means of a sealing device which ensures that the milk is protected from any adverse effects of external origin on its characteristics. The sealing device shall be so designed that once the container has been opened, the evidence of opening remains clear and easy to check.

SCHEDULE 10 Regulation 11(1)(d) and (4)
LABELLING AND HEALTH MARKING
PART I
LABELLING

1. In addition to the health mark requirements specified in Part II of this Schedule, the packaging of heat-treated milk **and liquid milk-based products** shall display visibly and legibly the following particulars **for control purposes -**

- (a) the nature of the heat-treatment applied to the milk;
- (b) adequate information, **which may be in code**, enabling the date of the last heat-treatment referred to in sub-paragraph (a) above to be established and, in the case of pasteurised milk, the temperature at which the product shall be stored.

2. Without prejudice to the provisions of Council Directive 79/112/EEC on the approximation of the laws relating to the labelling, presentation and advertising of foodstuffs for

sale to the ultimate consumer^(a), the labelling must show clearly for inspection purposes the following particulars -

- (a) the words "raw milk" for raw drinking milk intended for direct human consumption;
- (b) the words "made with raw milk" for milk-based products manufactured from raw milk whose manufacturing process does not include thermisation or heat-treatment;
- (c) in the case of milk-based products other than those referred to in sub-paragraph (b) above, the nature of any heat-treatment applied at the end of the manufacturing process;
- (d) for milk-based products in which the growth of micro-organisms can occur, the use-by or minimum durability date.

PART II

HEALTH MARK

1. Dairy products shall carry a health mark in an easily visible place. It shall be legible, indelible and its characters easily distinguishable.
2. Marking shall be carried out during or immediately after manufacture in the dairy establishment. The health mark may be applied to the dairy product, or to the wrapping, or to a label affixed to the wrapping in accordance with paragraph 5 below. Where a dairy product is individually wrapped and packaged or split into small packaged units to be supplied to the ultimate consumer by an institution* it shall be sufficient for the health mark to be applied to the packaging only.
3. Where a dairy product marked in accordance with paragraphs 1 and 2 above is subsequently placed in packaging, the health mark shall also be applied to that packaging.
4. Subject to paragraph 5 below, the health mark shall consist of an oval surround containing in legible form and in printed capital letters the following information -

(a) OJ No. L33, §2.79, p.1 to which there are amendments not relevant to these Regulations.

(a) either:

- (i) in the upper part, the letters "UK", followed by the approval number of the dairy establishment, and
- (ii) in the lower part, the letters "EEC";

(b) or:

- (i) in the upper part, the words "UNITED KINGDOM",
- (ii) in the centre, the approval number of the dairy establishment, and
- (iii) in the lower part, the letters "EEC".

5. In the case of bottles, packaging and receptacles referred to in Articles 11(4) and (6) of Council Directive 79/112/EEC^(a), the health mark may indicate only the initials of the consigning country and the approval number of the establishment*.

6. The health mark may be applied to the product, wrapping or packaging by an ink stamp or by branding, or it may be printed on or applied to a label.

7. The health mark may also consist of an irremovable plate of resistant material complying with hygiene requirements and bearing the information specified in paragraph 4 above.

^(a) OJ No. L33, §.2.79, p.1 to which there are amendments not relevant to these Regulations.

SCHEDULE 11
METHODS OF ANALYSIS

Regulation 10

1. The reference methods for the analysis and testing of dairy products in order to ascertain if they meet the requirements specified in Schedule 3, 4, 5 [and 6] shall be those specified in the following paragraphs of this Schedule.

2. In relation to raw milk and heat-treated milk, the methods shall be those specified in Commission Decision 91/180/EEC^(b) for the following:-

- (a) enumeration of micro-organisms - plate count at 30°C;
- (b) enumeration of somatic cells in cows' milk;
- (c) determination of phosphatase activity in cows' milk;
- (d) determination of peroxidase activity in cows' milk;
- (e) detection of pathogenic micro-organisms;
- (f) enumeration of coliforms - Colony count at 30°C;
- (g) enumeration of micro-organisms - plate count at 21°C;

3. In relation to milk-based products, the test for enumeration of micro-organisms-plate count at 30°C shall be the method specified in IDF standard 100B: 1991. Milk and milk products - micro-organisms - Colony count at 30°C;

4. In relation to milk-based products, the test for enumeration of coliforms shall be the method specified in ISO 5541 Part 2 1986. Milk and milk products - Part 2. Most probable number technique at 30°C.

[5. In relation to the following tests, the methods for the analysis and testing shall be those specified below -

^(b) OJ No. L93, 13.4.91, p.1.

<u>Test</u>	<u>Method</u>
(a) Detection of <u>Staphylococcus aureus</u>	Provisional IDF Standard 145:1990. Milk and milk-based products. Enumeration of <u>Staphylococcus aureus</u> in products other than dried milk-Colony count technique at 37°C.
(b) Detection of <u>Salmonella</u> spp	ISO 6579:1993. Microbiology - General guidance on methods for the detection of <u>Salmonella</u> .
(c) Detection of <u>Listeria monocytogenes</u>	ISO 10560:1993. Milk and milk products - Detection of <u>Listeria monocytogenes</u> .
(d) Detection of <u>Escherichia coli</u> in heat-treated milk products	Provisional IDF Standard []: 1993. Milk and milk products - Enumeration of presumptive <u>E.Coli</u> and coliforms. Most probable number technique with use of 4-methylumbelliferyl - β -glucuronide (MUG).
(e) Detection of <u>Escherichia coli</u> in raw milk products	Provisional IDF Standard []: 1993. Milk and milk products 1993. Milk and milk products - Enumeration of <u>E.Coli</u> . Colony count technique at 44°C using membranes.]

6. Any other internationally accepted analysis and test method as referred to in Article 20(1) of Council Directive 92/46 shall be recognized as a reference method.

7. In this Schedule -

"IDF standard" means a standard of the International Dairy Federation, and

"ISO" means a standard of the International Organisation for Standardisation.



**SCHEDULE 12
REVOCATIONS**

Regulation 22

Column 1	Column 2	Column 3
Milk and Dairies (Channel Islands and South Devon Milk) Regulations 1956	S.I. 1956/919	All the Regulations
Milk and Dairies (General) Regulations 1959	S.I. 1959/277	Parts II to VI, Parts VIII to X and Schedules 1 and 2
Milk and Dairies (Legal Proceedings) Regulations 1962	S.I. 1962/1288	All the Regulations
Drinking Milk Regulations 1976	S.I. 1976/1883	All the Regulations
Milk and Dairies (General) (Amendment) Regulations 1977	S.I. 1977/171	All the Regulations
Milk and Dairies (General) (Amendment) Regulations 1979	S.I. 1979/1567	All the Regulations
Milk and Dairies (Revision of Penalties) Regulations 1982	S.I. 1982/1703	All the Regulations
Milk-based Drinks (Hygiene and Heat Treatment) Regulations 1983	S.I. 1983/1508	All the Regulations
Milk and Dairies (Heat Treatment of Cream) Regulations 1983	S.I. 1983/1509	All the Regulations
The Food (Revision of Penalties) Regulations 1985	S.I. 1985/67	The reference to the Milk-based Drinks (Hygiene and Heat Treatment) Regulations 1983 in Part I of the Schedule
Milk and Dairies (Revision of Penalties) Regulations 1985	S.I. 1985/68	All the Regulations
Milk-based Drinks (Hygiene and Heat Treatment) (Amendment) Regulations 1986	S.I. 1986/720	All the Regulations
Milk and Dairies (Heat Treatment of Cream) (Amendment) Regulations 1986	S.I. 1986/721	All the Regulations
Importation of Milk Regulations 1988	S.I. 1988/1803	All the Regulations

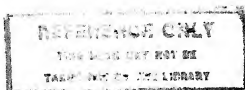
Column 1	Column 2	Column 3
Milk and Dairies (Semi-skimmed and Skimmed Milk) (Heat Treatment and Labelling) Regulations 1988	S.I. 1988/2206	All the Regulations
Milk and Dairies (Semi-skimmed and Skimmed Milk) (Heat Treatment and Labelling) (Amendment) Regulations 1989	S.I. 1989/2382	All the Regulations
Milk (Special Designation) Regulations 1989	S.I. 1989/2383	All the Regulations
Food Safety (Sampling and Qualifications) Regulations 1990	S.I. 1990/2463	The reference in Schedule 1 to the Milk-based Drinks (Hygiene and Heat Treatment) Regulations 1983, the Milk and Dairies (Heat Treatment of Cream) Regulations 1983, the Milk and Dairies (Semi-skimmed and Skimmed Milk) (Heat Treatment and Labelling) Regulations 1988 and the Milk Special Designation) Regulations 1989
Milk and Dairies (Semi-Skimmed and Skimmed Milk) (Heat Treatment and Labelling) (Amendment) Regulations 1990	S.I. 1990/2491	All the Regulations
Milk (Special Designation) (Amendment) Regulations 1990	S.I. 1990/2492	All the Regulations
The Food (Miscellaneous Revocations) Regulations 1991	S.I. 1991/1231	The reference to the Importation of Milk Regulations 1988 in the Schedule
The Food Safety (Exports) Regulations 1991	S.I. 1991/1476	The reference in the Schedule to the Drinking Milk Regulations 1976, the Milk-based Drinks (Hygiene and Heat Treatment) Regulations 1983, the Milk and Dairies (Heat Treatment of Cream) Regulations 1983, the Milk and Dairies (Semi-skimmed and Skimmed Milk) (Heat Treatment and Labelling) Regulations 1988 and the Milk (Special Designation) Regulations 1989
Milk (Special Designation) Regulations (Amendment) Order 1992	S.I. 1992/1208	All the Regulations
Milk and Dairies (Standardisation and Importation) Regulations 1992	S.I. 1992/3143	All the Regulations

ANNEX TO DRAFT REGULATIONS

EXPLANATORY NOTE ON ASTERIXES

The EC Commission have indicated that further amendments to the text of their proposals, as contained in COM(93)715, would be tabled. These are expected to be as follows:

- ◆ an extension of the deadline for unused packaging under Regulation 11(4) to 1 January 1996;
- ◆ provision for all limited production to be exempt from the requirement to use automatic sealing and filling equipment at Schedule 2, Part II, A, 2 and Schedule 9, 4;
- ◆ rewording of Schedule 2, Part II, 7 to provide for verification that milk has been properly pasteurised which need not include an automatic recording device;
- ◆ the production of other milk based products intended for use other than human consumption (eg skimmed milk powder or casein for industrial purposes) will be permitted providing the product is of the same quality as human foodstuffs at Schedule 2, Part III, 4;
- ◆ cows' milk may also be exempt from the storage and transport temperature requirements at Schedule 7, 2 and Schedule 8, 1 with the approval of the enforcement authority;
- ◆ small unit dairy products individually wrapped and packaged need not be supplied to an institution to benefit from the facility to put the health mark on the packaging only at Schedule 10, Part II, 2;
- ◆ more flexibility, in particular the separation of the approval number from the oval surround will be possible under labelling requirements at Schedule 10, Part II, 4;



- ◆ reusable glass bottles will be exempt from labelling requirements in Schedule 10, 1.
- ◆ Schedule 4, Part III, 7 is under consideration by the EC Commission because of its possible effect on the UK practice of double pasteurisation of low fat milk. In response to UK concerns on double pasteurisation, the Commission has proposed a temporary derogation for the UK for a five year period. Trade would be restricted to the national market and use of the EC health mark would not be permitted. The UK is seeking a solution that will be acceptable to UK industry;
- ◆ increase in plate count limits to 3 million for raw sheeps, goats and buffaloes milk prior to processing into heat treated drinking milk or milk for manufacture into milk-based products in Schedule 4, Part II 1(3) and Schedule 5, Part II 1(a).

The Commission has also proposed amending Annex A, Chapter IV of 92/46 to require samples from individual production holdings (and not bulked milk) to comply with the plate count and somatic cell count standards. At present Annex A allows testing at either the production holding or upon arrival at the treatment or processing centre. The UK is seeking to retain flexibility on testing sites and will authorise derogations from these standards under Regulation 15 until 1998. Trade would be restricted to the national market and use of the health mark would not be permitted.

These proposals will be discussed in Council Working Group before being put to the EC Council of Ministers for adoption.

PRELIMINARY COMPLIANCE COST ASSESSMENT

(DRAFT DAIRY PRODUCTS (HYGIENE) REGULATIONS 1994)

Purpose and Expected Benefits

1. The Regulations implement EC Directive 92/46 which harmonises EC hygiene rules over Community production and trade in milk and milk products. Provisions include structural requirements, hygiene and microbiological standards. Some amendments published in COM(93)715 are being discussed in Council Working Group.
2. These rules are intended to afford the same degree of protection to EC consumers throughout the Community and should open up new opportunities for competition.
3. Following review of existing legislation, it is proposed not to retain measures which exceed EC requirements except where there is a need to protect public health. These provisions are those relating to raw drinking milk (standards for which are to be extended to raw sheep and goats milk) and the heat treatment of cream and dairy ice cream.
4. Some provisions are similar to those under the EC Food Hygiene Directive due for implementation in December 1995, for example, hazard analysis systems, staff training and medical certification. The Department of Health are currently consulting the food industry as a whole on the costs of these measures and may obtain data that can be used for finalisation of this CCA.

Business Sectors Affected

5. The relevant business sector is 413 in the Business Monitor. There are approximately 29,000 cows milk producers and up to 2,000 dairies. The number of sheep and goats milk producers who will be registered for the first time is difficult to estimate but may be around 200. We have very little information on numbers of buffalo milk producers - there are likely to be very few.
6. Businesses affected will be all those involved in the production, processing and marketing of milk and milk products derived from cows, sheep, goats or buffaloes milk up to the point of retail.
7. Caterers (including shop premises, ice cream vans) are subject to heat treatment requirements for cream and ice cream and wholesalers not repackaging or rewrapping the product are subject only to storage and transport requirements.

8. Derogations from the more onerous requirements are available to dairies undergoing refurbishment, small businesses (and possibly production lines if EC amendments are adopted) using less than 300,000 litres per year, and specialist cheese manufacturers when the ageing process for their product is longer than 60 days.

Compliance Costs

9. These will depend on the size of the business and the derogations available and the nature of the product. Non-recurring costs may include structural refurbishment, the drawing up of a risk analysis programme, new equipment, new labelling, packaging and transport costs. Recurring costs may include veterinary checks, sampling, cleaning procedures and vermin control, transport costs. Premises may comprise both a farm or a farm and dairy or a dairy establishment alone. In general terms, ADAS inspect and register farms whereas EHOs inspect and approve dairies. Pre-registration and pre-approval visits are currently conducted by ADAS and EHOs free of charge but ADAS charge for inspection visits when a farm is registered (currently £94). Estimates in this cost compliance assessment of the costs arising from hygiene requirements are based on a preliminary ADAS study and consultations with the Department of Health and **will be revised in the light of information gathered from the industry during the consultation period.**

10. Non-recurring costs

(i) Small businesses

Small businesses producing and/or processing less than 300,000 litres of milk per year will include raw milk wholesalers, untreated milk and milk product processors, newly registered goats, sheep and buffalo milk producers/processors, and specialist cheese makers.

Farms

Structural refurbishment and equipment costs in the housing and milking parlour of a small farm with 50 cows could cost up to £1000-£1500 if refurbishment is necessary. This compares with the full cost of setting up second-hand housing and milking parlour equipment i.e. bail on a concrete pad, big bail silage, straw yard of £3000-£5000.

Information is not yet available for sheep and goats milk producers. This should become available under the Small Business Litmus Test. New equipment to pipe the milk to a refrigerated bulk tank could cost a small goat/sheep milker £5,000 - £6,000.

Dairies

Structural refurbishment for dairy establishments without derogation (separation of work areas, improved lighting and ventilation, improved wall, floor and ceiling finishes, hand washing and toilet facilities, chemical storage and storage areas) could lead to an additional cost of £1,000-£2,000 for a small typical dairy.

Full risk analysis assessments are not required, more a formal description of operations.

All dairy products up to the point of retail must also be packaged and labelled in accordance with the regulations and bear the approval number of the last dairy establishment on the commercial documentation and, with effect from 1 January 1995 (possibly 1 January 1996), on the packaging. This is not deemed to be an extra cost since many manufacturers periodically order new packaging. However there may be a need for new health marking equipment or redesigned labelling. Some provisional estimates have suggested between £200 and £1000 for the latter depending on the size of the business. **The industry are requested to supply costs on this.** Products for the national market must not be labelled or marked with the EC health mark.

(ii) Medium businesses

Medium-large businesses producing and/or processing from 300,000 to more than 1 million litres of milk per year and who may produce a range of products within the same establishment.

Farms

Structural refurbishment and equipment costs for a farm with 400 cows are similar to those for small farms though possibly with some economies of scale. This compares with the full cost of setting up new housing and new milking parlours of up to £1/2 million. If the decision were taken to invest in more sophisticated facilities then costs could be considerably higher.

Dairies

The structural and equipment costs of upgrading dairy premises are much the same as for small processors. The main difference is the requirement for mechanical filling

and automatic sealing equipment for bottling heat treated drinking milk and liquid products eg cream. Many medium-sized farm milk processors have invested in more sophisticated equipment such as rotary bottle fillers/sealers at a cost of between £5,000 to £12,000 (depending on whether second hand). Many have linked these to in line bottle washers and steam boilers at a cost of £10,000 to £20,000. Larger processors may also be investing in filling and sealing equipment for plastic bottles at a cost of £76,000 to £80,000. Some of these are not requirements of the new legislation.

Formal risk analysis assessments cost around £2,000 for the first product and £1,000 for each subsequent product. Large companies may also invest in laboratory facilities though these are usually in place for quality control purposes.

Investment in refrigerated vehicles (if required) for delivering milk to shops, supermarkets and milk retailers premises can cost from £15,000 to £80,000.

Labelling and health marking costs will be similar to those for small businesses.

- (iii) Caterers, shop premises (including ice cream vans) may only retail and market cream and dairy ice cream processed in accordance with the time/temperature combinations specified in the regulations. This is already a requirement under existing legislation and will not add to current costs of equipment to pasteurise and store dairy products.
- (iv) Wholesalers who repackage or rewrap dairy products are classified as dairy establishments and are accorded an approval number for tracing purposes though many requirements of the regulations will not apply. Wholesalers, cash and carries not repackaging or rewrapping will only need to meet storage and transport requirements. These are not onerous and are unlikely to entail additional costs.

11. Recurring costs

- (i) For all size of farm:
 - cleaning costs have been estimated at £25 per cow;
 - relief labour to cover for illness (when an employee has an illness which could be transmitted to humans via milk) at £200/week;
 - raw milk tested for microbiological standards by a private laboratory at £16 per sample plus £5 - £15 per sample for collection depending on the distance (ADAS

charge separately for the sampling of raw cows drinking milk sold direct to the ultimate consumer currently £63, a price inclusive of collection and administrative costs);

- veterinary checks: TB and brucellosis blood tests are conducted free of charge by SVS staff and LVIIs. Other checks are dependent on private veterinary fees (current rate around £40 per hour).
- labelling costs (Industry are requested to supply figures on additional recurrent costs).

(The annual profit of small producers is estimated at £4000-£6000)

(ii) For all size of dairy,

- hygienic daily processing of 100 gallons of milk into pasteurised drinking milk has been estimated at £140. This includes cleaning and vermin control, labour, packaging, milk sample analysis, maintenance and insurance of buildings and equipment. It does not include the costs of purchasing the raw milk, labelling milk products and refrigerated transport where necessary.

Estimates have not been made for other dairy products such as cheese, yoghurt, cream, dairy ice cream etc. because of the diversity of products which may be processed. [Relevant industry sectors are requested to supply figures].

Total Compliance Costs

12. There are estimated to be a total of 11,500 farms with less than 50 cows using milk for catering purposes or wholesaling and retailing milk, the equivalent number with 50-100 cows, and just over 6,000 with more than 100 cows. Information on numbers of sheep, goat and buffalo milk producers is not yet available. Central figures have not been collected for approved dairy establishments until now. The number of notifications of approval received by Milk and Milk Products Division from Environmental Health Departments presently stand at around 1050.

13. The type of investments made to upgrade buildings and equipment can vary significantly from farm to farm. There are a number of reasons for this, as follows:

- (i) Dairy units are subject to continual refurbishment and many units set up in the 1970s are now in need of refurbishment irrespective of the new regulations which do

not differ greatly from current legislation affecting cows milk producers. The possible exception to this are sheep, goat and buffalo milk producers who are not subject to detailed legislation at present (apart from general food hygiene legislation).

(ii) Many investments being undertaken are not directly required by these Regulations. The UK dairy industry is entering a transition period, moving from highly managed markets to more open trading conditions. There is a sense of optimism and buoyancy among many UK dairy farmers at present, with good profits yielding capital for investment which includes £5m in England and Wales, £1.5m in Scotland and N Ireland recently made available from the EC Co-responsibility levy in the UK. The opportunity is therefore being taken by some sectors of the industry to expand or develop businesses as a future guarantee of income and security over the coming years.

(iii) Temporary derogations allowing for refurbishment and exemptions from mechanised filling and automatic sealing equipment (a particular problem in the UK) have been available to these businesses irrespective of size. Products produced by these establishments may not however be traded outside the UK or bear the EC health mark. The UK list of some 500 establishments seeking such derogations has now been agreed by the Commission.

(iv) EHOs have been authorised to exempt small product processors from most of the structural and equipment requirements of the regulations except those pertaining to general conditions of hygiene and the risk analysis programme (though a full HACCP is not required for small businesses). On the basis of data received so far, we are aware of some 350 processors who have been given a permanent derogation.

(v) Recurring costs are dependent on the volume and type of dairy products processed.

14. The recurring and non-recurring costs for individual dairies will vary greatly according to the size of premises and products manufactured, the derogations authorised by EHOs, and the final outcome of negotiations to amend the Directive. Total compliance costs can therefore only be estimated on the basis of final numbers and information supplied by the industry during the consultation period.

Small Business Litmus Test

15. This will be dealt with as part of the consultation exercise.

Effects on International Competitiveness

16. It is unlikely that there will be much impact on international competitiveness since industry in other Member States will be subject to EC requirements. National provisions being retained will affect only a very small sector of the industry.

Arrangements for Monitoring and Review

17. The effects on industry will be kept under review and a final CCA drawn up based on information obtained during the consultation period.

Alternative Approaches.

18. To comply with our Community obligations, it has been necessary to implement the Directive on milk hygiene. In the interests of public health some national measures have also been retained. A more regulatory approach would have been possible but contrary to Government policy. Instead we have deregulated and consolidated national legislation where possible. During negotiation of technical amendments to the Directive we have also sought to secure more flexibility in implementing its provisions, such as health mark labelling, and to extend the provisions for derogation from the more onerous requirements. We will continue to negotiate in the Community for a more deregulatory approach where possible.

19. In seeking to implement the Directive sensibly into our national legislation, we are intending to employ existing Food Safety Act procedures wherever possible to minimise burdens on businesses whilst meeting our Community obligations.

DRAFT July 1994

Ministry of Agriculture, Fisheries and Food

Department of Health

Scottish Office

Welsh Office

FOOD SAFETY ACT 1990

Code of Practice No []

**Enforcement of the Dairy Products (Hygiene) Regulations 199[4]
("the Regulations")**

DRAFT CODE OF PRACTICE: ENFORCEMENT OF THE DAIRY PRODUCTS (HYGIENE) REGULATIONS 199(4) ("THE REGULATIONS")

The sections in **bold type** are a Code of Practice issued under Section 40 of the Food Safety Act 1990 to which food authorities must have regard. The remaining text is for information only.

Introduction

1. This Code of Practice gives guidance to food authorities on the requirements of the Dairy Products (Hygiene) Regulations 199[4] (and Dairy Products (Hygiene) (Scotland) Regulations 199[4]). The Regulations, which include several Schedules, implement the requirements of Council Directive 92/46 laying down rules for the production and placing on the market of raw milk, heat-treated milk and milk based products from cows, sheep, goats, and buffaloes intended for human consumption (and Directive 92/47 on the conditions for granting temporary and limited derogations from specific requirements in Directive 92/46). [Certain amendments to Directive 92/46 (in COM(93)715) are currently under discussion]. The Regulations also include a few provisions from existing legislation which, following review, have been retained (and in the case of standards for raw drinking milk extended to sheep and goats milk) on public health grounds.
2. This Code explains the role of food authorities in the monitoring and enforcement of the Regulations and should be read in conjunction with other statutory Codes of Practice under the Food Safety Act and in particular Code of Practice No 9: Food Hygiene Inspections (Revised) and No 7: Sampling for analysis or examination. When more specific requirements are set down in this Code, these should take precedence.
3. Food authorities should also follow guidance issued separately by central government.
4. Where difficulties of interpretation arise, authorised officers should discuss these with the local co-ordinating group (in England and Wales this is established under Code of Practice No 1: Responsibility for Enforcement of the Food Safety Act 1990) . If this does not resolve the matter the issue should be referred to the relevant panel of the Local Authorities Co-ordinating Body on Food and Trading Standards (LACOTS). In Scotland, any difficulties should be referred to the Scottish Food Co-ordinating Committee (SFCC) and its Local Liaison Groups. Food authorities should, wherever possible, avoid taking unilateral decisions on interpretation.

5. Food authorities should be guided by LACOTS' home authority principle in determining which food authority should take lead responsibility for giving advice to food businesses which have more than one branch or unit situated in different food authority areas. [A separate procedure may be established in Scotland.]

6. Matters of policy on the Regulations and this Code and significant enforcement issues will be considered by the Liaison Committee consisting of MAFF, DH, [SOAFD], WOAD, [DANI AND DHSS (NI)] AND LACOTS in England and Wales [SFCC in Scotland]. Food authorities should have regard to any advice or opinion given by that Committee. Where no central guidance has been issued the food authority should have regard to any advice or opinion given by the appropriate national co-ordinating body - LACOTS in England and Wales [SFCC in Scotland]. Where a food authority wishes to adopt an approach which is not consistent with advice issued by the national co-ordinating body, they should first discuss their approach with that body.

COMPETENT AUTHORITY

7. MAFF (and SOAFD in Scotland) is the central competent authority, i.e. the central Government department with lead responsibility for these Regulations. For the purposes of enforcement at a local level, food authorities (and in certain cases the appropriate Minister) are the competent authorities. Food authorities will approve dairy establishments (and in Scotland licence production holdings) and will also enforce all aspects of the Regulations except in the cases listed below.

- Requirements relating to registration of production holdings in England and Wales (- this will be dealt with by MAFF (ADAS)). Separate guidelines will be issued for enforcement of these requirements.
- Controls on production of and standards in Schedule 4 Part 1 para 2 for raw cows' drinking milk sold direct to consumers in England and Wales) (-this will be dealt with by MAFF (ADAS)).
- Checks on the health of animals (- this will be dealt with by Agricultural Departments but see Schedule 3 Part I).

- **NB:** In England and Wales where a premise is both a production holding and a processing establishment the appropriate Minister will be responsible for registering it as a production holding and approval of the processing part of the premises will be the responsibility of the food authority.

8. It will be for the appropriate competent authority to establish if the premises are subject to the Regulations. In England and Wales where there is doubt relating to the location of a processing premise on the same site as a production holding, which has been registered by MAFF, food authorities should consult their local MAFF - ADAS office. Food authorities in England and Wales should liaise with ADAS in respect of premises which are also production holdings in order to minimise problems for operators and notify ADAS in cases where they suspect that any person or a production holding is suffering from an infectious disease. They should also bear in mind the liaison arrangements laid down in Code of Practice No 1 (Responsibility for Enforcement of the Food Safety Act 1990). ADAS should liaise with food authorities in respect of processing premises which are also on a production holding.

SCOPE OF REGULATIONS

9. The Regulations cover premises engaged in
- (a) production of raw milk (production holdings);
 - (b) heat-treatment of milk (treatment establishments); and
 - (c) manufacturing, preparing, processing, (including slicing, packaging, bottling, wrapping or re-wrapping) of any dairy products (processing establishments).

In addition, storage depots and wholesalers etc are subject to certain storage and transport provisions. Certain retail premises selling dairy products are exempt (see paragraphs 12 and 13 below).

Definitions

Milk

10. Milk is defined in Regulation 2. It includes raw milk as well as milk that has undergone some form of heating, i.e. thermisation, pasteurisation, UHT, sterilisation.

Milk-Based Products

11. The EC Commission has advised that milk-based products should be defined as:

- (a) milk products - whey, cream, cheese, butter, butter milk, butter oil, anhydrous milk fat, yogurt, kefir, partly or wholly dehydrated milk products, caseins, caseinates and lactose and
- (b) composite milk-based products which are products where:
 - (i) no part replaces or is intended to replace any milk constituent; This means that a half-fat butter where all of the fat is dairy fat and the rest of the product is water would be within the scope. However a yellow fat spread containing mainly butter plus a small amount of vegetable fat would not be a composite milk based product.

AND

(ii) milk or milk product is an essential part either in terms of quantity or for characterisation of the product. The Commission has prepared a document which helps to clarify the type of composite milk products within the scope of the Directive. According to this document, the crucial factor is the definition of "essential part" so that products containing small amounts of milk or milk products are excluded, e.g. milk chocolate, biscuits containing butter, whisky cream. The document does not specify a percentage of milk/milk products, but a guideline figure of 50% is inferred. A composite milk product may contain less than this amount of milk/milk product if the milk ingredient is essential in terms of characterisation. Examples of composite milk products are dairy ice cream and dairy desserts such as creme caramel and custard. If food authorities are unclear as to whether a product is a milk-based product they should contact MAFF (or SOAFD in Scotland) with details of the composition of the product. The Commission may issue further advice in this area in due course.

[The Commission has also issued guidance on products falling with Article 18 of the Directive e.g. non-dairy ice cream and the rules that would apply to them. Such products cannot bear a health mark. The regulations do not at present cover these products pending further clarification in Brussels].

Exemptions

12. Premises which are producing or handling dairy products solely for their own consumption or supplying other than in the course of a business, are exempt from all provisions in the regulations. In addition catering establishments and shop premises selling dairy products, are exempt from provisions except those relating to raw cows milk in Regulation 12 and heat-treatment of cream and ice cream in Schedule 6. This exemption is intended to cover premises such as cafes, caterers, ice cream vans, milk floats, shops, and bakers (and applies whether they are selling direct to the ultimate consumer or supplying other retail outlets eg pubs).

13. It is not the intention that the Regulations will apply to domestic production which supplies the ultimate consumer through outlets such as markets operated by the Women's Institute or charities or to meals on wheels catering operations. However any premises handling dairy products that are not covered by the Regulations will remain subject to the Food Hygiene (General) Regulations 1970 (as amended) or the Food Hygiene (Scotland) Regulations 1959 (as amended). (To be replaced by the Food Safety (General Food Hygiene) Regulations when implemented.)

Processors/retailers of raw milk/raw milk products

14. There is some discretion in the Directive for Member States to set their own rules for sales of raw milk or raw milk-based products made direct by producers to consumers. Ministers have now agreed that on-farm processors of raw drinking milk (ie those wrapping/bottling raw milk) or raw milk-based products produced on the farm premises who sell their entire output of such products direct to the ultimate consumer should be exempt from approval. However such processors will need to meet general hygiene requirements for processing establishments in Schedule 2 Part III of the Regulations and requirements in Regulation 13 on duties of occupiers. If any of their sales are to cash and carries etc or to other retail outlets they would need to be approved. In England and Wales existing restrictions on sales of raw cows drinking milk will continue - as provided for in Regulation 12 of the Regulations. ADAS will enforce these provisions at farm level for the present but food authorities will be responsible for sales by distributors. In Scotland

sales of raw cows drinking milk are prohibited. The exemption in Scotland will only apply to processing premises selling their entire output of raw goats and sheep milk and/or raw milk-based products made on the farm premises direct to the ultimate consumer.

Derogations

Temporary

15. In accordance with arrangements under Directive 92/47, establishments were able to apply for temporary derogations (applicable until 1 January 1998) from requirements in Annex B Chapter I and V of Directive 92/46 (Schedule 2, Part I of the Regulations). Food authorities have been separately notified of establishments in their area whose applications were forwarded to Brussels and which have subsequently been agreed in Commission Decision [94/]. (In the light of subsequent amendments to Directive 92/46 many of these temporary derogations may no longer be necessary). Establishments granted temporary derogations will need to be approved but their products do not qualify for an EC health mark. Where establishments with temporary derogations complete necessary works to meet the full requirements of the Directive as agreed with food authorities they can be advised that their products do qualify for an EC health mark. If they do not undertake necessary work within the required deadline, food authorities will need to consider appropriate action. Food authorities should advise MAFF/SOAFD when necessary work has been completed so that this information can be passed to the EC Commission.

16. Directive 92/47 also enables Member States to grant temporary derogations to establishments which cannot obtain supplies of raw milk meeting plate count and somatic cell count standards in Schedule 3 of the Regulations. Regulation 15 implements this provision, but it leaves it to establishments to decide whether to operate under a temporary derogation. Such derogations may be necessary if a Commission proposal to require measurement of standards only in relation to milk from one production holding succeeds. However the UK is opposing this proposal in Brussels. Again any establishment operating with a temporary derogation could not health mark the product affected or export it to other Member States.

Permanent

17. Regulation 6 allows food authorities, when considering approval, to grant derogations from certain equipment and building requirements in Schedule 2 to low capacity establishments making milk-based products which use no more than 300,000

litres of milk (or equivalent in terms of milk products) per year. Establishments solely producing liquid milk as the end product are not currently eligible for these derogations (although we are seeking to have this changed in Brussels). Since most of the requirements in Schedule 2 are similar to those in existing cows milk legislation, there are likely to be few cases where food authorities will need to consider granting permanent derogations to processors of cows milk products. However, goat and sheep milk product processors may experience more difficulty in meeting requirements and permanent derogations may be necessary in some cases.

18. One problem area for industry is the need for equipment for mechanical filling and automatic sealing of containers of heat treated milk and liquid milk based products e.g. cream. However the EC Commission has proposed an amendment to the Directive which would exempt limited production processors of both heat treated drinking milk and liquid milk based products (this would include low capacity establishments i.e. those using no more than 300,000 litres of milk per year as well as establishments with limited production lines) from the need to mechanically fill and automatically seal containers. Establishments with limited production permanent derogations need to be approved and their products do qualify for an EC health mark.

19. Food authorities should note that Regulation 9 allows derogations from certain requirements for manufacturers of long keeping cheeses. It is thought that very few businesses would be eligible under this category. Food authorities should advise MAFF of any cases that might fall into this category.

ELIGIBILITY FOR TRADE WITH OTHER MEMBER STATES

20. Only establishments approved under these Regulations and whose products bear an EC health mark (including the approval number of the establishment) can trade their products with other Member States. (The position of trade with other EEA states is currently being considered). Establishments with temporary derogations cannot use an EC health mark on their products and can sell only on the UK market.

APPLICATIONS AND APPROVAL OF ESTABLISHMENTS

21. Separate guidelines have already been issued to food authorities relating to approval of establishments. From the date of entry into force of this Code the following guidance updates and replaces these guidelines.

Applications

22. Responsibility for applying for approval rests with the occupier. Applications must be made in writing to the food authority. Food authorities should ensure that at the earliest opportunity they discuss with potential applicants the requirements of the regulations and the timing of applications. Wherever possible this should be achieved during a routine inspection carried out in accordance with Code of Practice No 9 (Revised): Food Hygiene Inspections.

23. All establishments involved in heat treatment of milk, or treatment and/or processing and/or wrapping of dairy products must be approved (including those with temporary and permanent derogations). In addition collection centres and standardisation centres must be approved. Stand alone storage depots, distribution warehouses, cash and carries do not need to be approved assuming they are not carrying out any processing e.g. packing.

Approvals

24. Food authorities should deal promptly with any operator seeking approval. Where the authority is satisfied that the establishment meets the relevant requirements of the Regulations it should notify the applicant in writing of its decision. It shall then allocate to each establishment a unique identification reference which shall be known as the approval number. Food authorities should issue one approval number to establishments also covered by other product specific regulations e.g. meat products. Where an establishment carries out a number of separate processing activities covered by the Regulations e.g. cheese manufacture and cheese packing or has a number of separate production lines make different products, a single approval number should be allocated which will apply to all those activities at one location which require to be approved under the terms of these Regulations. Separate advice has been issued by MAFF and SOAFD on the system for numbering approved premises.

25. Approval is subject to continuing compliance with the Regulations and food authorities will wish to draw this to an operator's attention when granting approval. Whilst the responsibility for informing food authorities of any significant alterations to methods of operations (including processes), premises or equipment (other than by way of maintenance or repair) remains with the operator, food authorities should develop links with occupiers of approved establishments to facilitate communication of such information.

26. Food authorities may also approve an establishment where only a part of those premises is engaged in the handling of dairy products, providing all conditions relating to the handling of the dairy product meet the requirements of the Regulations relating to approval and the hygiene of the dairy product is not adversely affected by the other foodstuffs. Any health mark is limited to those dairy products. There may be premises where two or more vertical directives and subsequent implementing regulations apply - for instance establishments dealing with meat products and dairy products. In such cases the appropriate directive and implementing regulations will apply to the respective areas and in areas of shared facilities the provisions of the directive and implementing regulations with the higher standards apply.

27. Where approval is refused the food authority must notify the applicant in writing of the reasons and the actions necessary to comply with the relevant requirements of the Regulations.

RIGHT OF APPEAL

28. Occupiers have the right of appeal to Magistrates (in Scotland to the Sheriff), if approval has been refused. Food authorities should make occupiers aware of their right of appeal. Wherever possible they should deal promptly with any proposal by the occupier where this would avoid the need for a formal appeal.

REVOCATION OF APPROVALS

29. Regulation 8 includes provisions intended to meet the UK's obligation to implement a specific Directive provision requiring the approving authority to have the power to revoke approvals. Food authorities should only exercise the revocation power when a previously approved establishment has been made the subject of a Prohibition Notice or Emergency Prohibition Order under the Food Safety Act and has effectively ceased to trade as a result. The only exception to this is where a business has ceased to handle milk and milk products in which case an approval can be revoked without Food Safety Act procedures having been gone through - although there will be a right of appeal for businesses to the Magistrates Courts (Sheriff Courts in Scotland).

RETURNS TO CENTRAL GOVERNMENT

30. A central list of all approved dairy establishments in the UK will be maintained by MAFF. These lists will form the basis of information sent to the EC Commission and other Member States where necessary and may be used to assist in response to food safety incidents. Food authorities in England and Wales should send information relating to approvals to MAFF and authorities in Scotland to SOAFD (who will copy to MAFF) immediately any approval is granted using the appropriate form (MK19). MAFF [or SOAFD as appropriate] must be informed of any subsequent changes to the information on the approval form or if the company in question ceases to trade, changes its name or address or immediately a prohibition order including an emergency prohibition order is issued (or lifted) under the Food Safety Act 1990.

APPLICATIONS FOR LICENSING OF PRODUCTION HOLDINGS IN SCOTLAND

31. In England and Wales ADAS will deal with production holdings. In Scotland food authorities do so. Responsibility for applying for licensing rests with the occupier. Applications must be made on the appropriate form to the food authority. Food authorities should ensure that at the earliest opportunity they discuss with potential applicants the requirements of the Regulations and the timing of applications.

Licensing

32. Food authorities should deal promptly with any producer seeking a licence. Where the authority is satisfied that the production holding meets the relevant requirements of the Regulations it should notify the applicant in writing of its decision. It should allocate to each a unique identification reference which shall be known as the licence number.

33. Licensing is subject to continuing compliance with the Regulations and food authorities will wish to draw this to operators attention when granting a licence. Whilst the responsibility for informing food authorities of any significant alterations to methods of operations, premises or equipment (other than by way of maintenance or repair) remains with operators. Food authorities should maintain links with occupiers of licensed production holdings to facilitate communication of such information.

34. Where a licence is refused food authorities must notify the applicant in writing of the reasons and the actions necessary to comply with the relevant requirements of the Regulations.

RIGHT OF APPEAL - SCOTLAND

35. Producers have the right of appeal to the Sheriff if Licensing has been refused. Food authorities should make producers aware of their right of appeal. Wherever possible they should deal promptly with any proposal by a producer where this would avoid the need for a formal appeal.

RETURNS TO CENTRAL GOVERNMENT - SCOTLAND

36. Food authorities in Scotland will maintain a list of all licensed production holdings in their areas and keep these up to date so they can be immediately available to SOAFD as required.

HEALTH MARKING

37. It is the responsibility of the occupier to ensure that the health mark is properly applied (Regulation 13(1)(e)) and that products are not marked with a health mark when they are not entitled to be (Regulation 15(2)). Food authorities should satisfy themselves that these requirements are met and that other precautions are taken to avoid any confusion between dairy products with a health mark and those products without such a mark (Regulation 15(5)(b)).

38. The EC Commission has proposed a delay in the introduction of health marking requirements (until 1 January 1995 - expected to be extended to 1 January 1996) during which time products can be traded without a health mark provided that the health mark (or the approval number) is shown on the commercial document accompanying the product. (They have also said that products manufactured and wrapped before 1 January 1995/6 would not need to be health marked). Food authorities should allow occupiers of establishments to use existing stocks of labels or pre-printed wrapping or packaging material until 1 January 1995/6 (unless their labelling needs to be changed to reflect other labelling requirements in the Directive - although this is likely to be rare)).

39. Food authorities should issue approval numbers without delay in order to allow establishments to make early progress in producing new packaging materials.

CERTIFICATION OF PRODUCTS AND USE OF COMMERCIAL DOCUMENTS

40. Dairy products (other than raw milk) and heat treated milk for manufacture of milk products must be accompanied during transport by a commercial document (e.g. an invoice, consignment or delivery note) issued by the occupier of the last establishment. This needs to bear a number of details as specified in the draft Regulations. Schedule 8 provides further information on commercial documentation.

41. Health certification of dairy products consigned to another Member State is not required. [Existing third country certification arrangements for dairy products exported to those countries remain unaffected by these Regulations (at present)].

OCCUPIERS RESPONSIBILITIES - FOOD AUTHORITY ROLE

42. The Regulations place primary responsibility for compliance on the occupiers of establishments (and in some cases also first purchasers of raw milk). Under Regulation 13 "the occupier" must meet a number of key requirements related to production systems; these include the need to identify any points that are critical to the processes used and to establish and implement methods monitoring and checking them. **In determining whether occupiers have met the requirements of Regulation 13, authorised officers should consider only those matters affecting food safety to form judgements about the acceptability of the measures taken.**

Critical points for the Safety of Dairy Products

43. In addition to the inspection of the structure of the premises, authorised officers should satisfy themselves that any process controls are in accordance with the conditions specified by the Regulations and the approval relating to the establishment. An examination of relevant process controls, as required by Regulation 13, should form an integral part of the inspection. Code of Practice No 9 (Revised): Food Hygiene Inspections outlines the importance of the risk assessment approach towards ensuring food safety.

44. In deciding whether the occupier has satisfied the requirement to identify and check critical points, authorised officers should recognise that the Regulations do not specify that a formal Hazard Analysis and Critical Control Point appraisal should be carried out. There may be other similar techniques or approaches which would

enable the occupier to identify critical points. For the purposes of the Regulations critical points are only concerned with food safety.

45. Authorised officers should normally expect to find some form of documented food safety management system in place but the extent of the documentation necessary will be determined by the scale of the operation, the nature of the process and the nature, packaging and storage of the final products. Some occupiers may identify only a few critical points and their controls may be simple and straightforward. An authorised officer should not insist on full documentation and records in such cases.

46. Whilst authorised officers are not expected to undertake an in depth evaluation of the controls identified, they should exercise their professional judgement to assess whether the critical points have been identified. The level of expertise required by the occupier to enable him to identify the critical points will be determined by the complexity of the food process.

47. Authorised officers should pay particular attention to the critical points identified by occupiers and establish whether the control measures identified are being implemented and recorded and where appropriate necessary corrective action is taken.

Assessment of Cleaning and Disinfection Method

48. In assessing compliance with Regulation 13(1)(b)(v), food authorities should ensure that cleaning chemicals, such as detergents or disinfectants are suitable for use in food production and are used in accordance with any instructions issued by the manufacturer. Authorised officers should expect to find written cleaning schedules listing chemicals in use and should consider the acceptability of programmes in place together with any laboratories used, in accordance with their existing enforcement practices bearing in mind the scale of the operation, the nature of the process and the nature, packaging and storage of the final product. Where laboratories are used, they may be based on the premises or elsewhere, including in private laboratories off site.

49. The reference to the need to take samples for checking the effectiveness of cleaning methods in Regulation 13(1)(b)(v) should not be interpreted by authorised officers as a requirement that all occupiers must take microbiological samples although many businesses may do this as part of their normal management systems.

Training Requirements

50. When considering the acceptability of food hygiene training programmes drawn up by occupiers, food authorities should have regard to the requirements of Code of Practice No 9 (Revised): Food Hygiene Inspections.

Medical Certification of Employees

51. The requirement for personnel working on or handling raw materials and dairy products (Schedule 2 Part III B1) to prove by medical certificate that there is no impediment to such employment only applies to staff on recruitment to the business. Those staff already in post prior to premises being approved are not subject to this provision. There is no requirement for annual medical certification. Previous guidance on medical certifications was issued to medical practitioners in England and Wales by the Department of Health in 1979 under A/E100/18. The decision on whether to issue medical certificates will rest with a medical practitioner registered with the General Medical Council and may be based on any investigation that the practitioner considers necessary. At the discretion of the employer, possibly based on a questionnaire, a health certificate issued in respect of a recent previous period of employment may be acceptable. Further advice is expected to be issued shortly [by Department of Health/SOAFD].

Notification of Health Risks by Occupiers

52. Where an occupier or purchaser of raw milk notifies the food authority in accordance with the regulations that their checks have revealed a serious health risk in connection with a product the food authority should have regard to Codes of Practice No 4: Inspection, Detention and Seizure of Suspect Food and No 16: Food Hazard Warnings.

Schedules

53. Guidance on aspects of the Schedules to the Regulations is set out in the Annex attached.

APPROACH TO INSPECTION

Authorised Officers

54. Before authorising an officer to carry out inspections of establishments the food authority should be satisfied that the officer is competent to do so, is suitably qualified and possesses the necessary experience which would allow him to undertake the duties: [Code of Practice No 9 (Revised): Food Hygiene Inspections sets out relevant qualifications for officers undertaking inspections]. Food authorities should give particular attention to the need for authorised officers to receive appropriate training in HACCP.

55. Food authorities should ensure that officers authorised to carry out inspections of establishments or undertake enforcement activities under the Regulations are fully aware of the content of the Regulations and this Code of Practice and continue to receive appropriate training. Food authorities should also ensure that these officers are aware of the content of other relevant Codes of Practice under the Food Safety Act 1990.

Frequency

56. In deciding the frequency and approach to inspections, food authorities should have regard to Code of Practice No 9 (Revised): Food Hygiene Inspections particularly regarding inspection ratings.

Reports

57. On completion of the inspection, the officer should discuss with the occupier or his representative (or if appropriate the purchaser of raw milk) a summary of the matters which in the opinion of the officer breach the requirements of the Regulations and any advice on good food hygiene practice he may need to give. The officer should submit a written report in accordance with Code of Practice No 9 (Revised): Food Hygiene Inspections.

Enforcement Action

58. A food authority has a range of options available when breaches of these Regulations are identified during an inspection. Advice on the enforcement action

possible is contained within Code of Practice No 5: The Use of Improvement Notices and Code of Practice No 6: Prohibition Procedures. In deciding what action should be taken when breaches of Regulations are identified, the officer should have regard to advice contained in other relevant Codes of Practice. Food authorities must clearly distinguish between recommendations which might be appropriate on the basis of good manufacturing practice and those considered necessary to satisfy the requirements of the Regulations.

Monitoring the Quality of Inspection

59. Food authorities should ensure that the documented procedures which exist within the authority to monitor the quality and nature of inspections undertaken by their officers incorporate the requirements of the Dairy Products (Hygiene) Regulations, and the Dairy Products (Hygiene) (Scotland) Regulations, the guidance contained in this Code of Practice and other guidance issued separately by central Government. Food authorities should have particular regard to provisions on monitoring inspections in Code of Practice No 9 (Revised): Food Hygiene Inspections.

SCHEDULE 1

GENERAL CONDITIONS OF HYGIENE FOR PRODUCTION HOLDINGS

Part I

Animal Identification

1. In paragraph A1 the requirement applies to both milking and dry stock. Females close to parturition should also be kept in accordance with this requirement.

Milking Equipment Storage

2. In paragraph A3 there would be an exception for animals kept in stalls and milked directly into a milk line which was fitted permanently in that building. (For example a cowshed fitted with a milk pipeline.)

Pigs and Poultry

3. In paragraph A4 some large open span buildings where pigs are housed at one end and milking animals at the other may be permitted providing no smell or contamination reaches the milking area.

Vermin Control

4. In paragraph A6 it should be noted that this also applies to infestation in adjacent buildings, feed stores etc. Appropriate measures should be in place to prevent birds from entering milking areas and milk rooms even if it requires modifications to buildings.

Clean Clothes

5. In paragraph B1(a) although recommended, they need not be waterproof as long as they are clean.

Illness

6. In paragraph B3 there is no requirement for annual medical certification to confirm this point.

Part II

Conditions for housing of animals

Design and construction

7. In paragraph 1 evidence of dirty animals, inadequate bedding, stale or foul air, overcrowding or physical damage such as swollen hocks would be regarded as unsatisfactory.

Bedding

8. In paragraph 2 in practice it would be difficult to achieve a satisfactory standard of animal cleanliness unless some bedding is used.

Disinfectants

9. In paragraph 3 outhouses refers to feed stores or isolation premises. Strong smelling or phenolic disinfectant liable to contaminate milk should not be used. (Generally disinfectants should be regarded as acceptable provided they are suitable for use with foodstuffs and are used in accordance with the manufacturer's instructions).

Part III

Structure of the premises

10. In paragraph A1(a) there should be no direct access between the milk storage room and animal housing.

Walls and flooring

11. In paragraph A1(b) normally good quality concrete for floors and good quality cement rendering on walls will be adequate. However in some areas

painting cement rendering with a durable waterproof paint or fitting impervious sheeting may be required. Tiles or plastic sheeting can be satisfactory if properly installed and maintained. Wooden materials should be avoided but if they are fitted must be painted or sheeted to facilitate cleaning.

Ventilation and Lighting

12. In paragraph A1(d) natural lighting should be provided if at all possible and supplemented by sealed unit fluorescent strip lights if possible. Air bricks in external walls and/or mechanical ventilation may be necessary to avoid excessive condensation.

Water supply

13. In paragraph A1(e) if water other than mains is used within the milking premises it is most important that there is no risk of contamination of the milk by the splashing of equipment by such water. Only potable water should be available in the milk room. If there is concern about the standard of water being used, this should be reported to the local food authority.

Equipment cleaning

14. In paragraph B3 the requirement to rinse with potable water does not apply where the disinfectant is specifically designed not to be rinsed off after application, nor does it apply where disinfection is by steam. Adequate supplies of heated water should also be available.

Moveable Bails

15. In paragraph C2c this means frequent moves to a fresh area of pasture but in wet conditions this could be every day to avoid accumulations of mud and dung occurring.

Feed Storage

16. In paragraph D1 this should not prohibit the use of a feed loft above the milking area. However, the use of any type of feed which creates a dusty atmosphere in the premises during milking should be prohibited.

Part IV

Milking Conditions

17. In paragraph 1 the feeding of dusty or strong smelling feeds, the use of dusty bedding materials close to the milking premises, and application of certain chemicals to animals might have an adverse effect.

Udder Disease

18. In respect of paragraph 4 whilst milking diseased animals last is often good practice it may not always be practicable on all farms and so it will be necessary in many instances for separate milking equipment to be available to milk animals with udder disease during milking.

Teat dips

19. Regarding paragraph 5, in most cases teat dips/sprays will have been licensed by the Veterinary Medicines Directorate (VMD) under the Medicines Act. Authorities should be able to tell from the manufacturer's instructions whether the dips/spray could be safely used before milking.

SCHEDULE 2

HYGIENE CONDITIONS FOR DAIRY ESTABLISHMENTS

Part I

Potable Water

1. The requirement in paragraph 1 (g) for a supply of potable water may be a problem for some processors e.g. on farms whose supplies may not, in all respects, meet the requirements of the Private Water Supplies Regulations 1991. DoE Circular 24/91 (Welsh Office Circular 68/91) gives guidance to local authorities on their duties under these regulations including action that should be taken to improve supplies. General queries on the Private Water Supplies Regulations in England may be sent to the Department of Environment, Water Services Division, Room A4/40, Romney House, 43 Marsham Street, London SW1P 3GB. In Wales queries should be sent to Welsh Office Environment Division, 2nd Floor, Cathays Park, Cardiff, CF1 3NQ. In Scotland, the relevant regulations are the Private Water Supplies (Scotland) Regulation 1992. Guidance to local authorities has been issued by the Scottish Office and general queries should be sent to Scottish Office Environmental Department, Engineering, Water and Waste Directorate, 27 Perth Street, Edinburgh, EH3 5RB.

Changing rooms

2. Food authorities should note that in respect of paragraph 1 (h), a separate changing room will only be necessary where the size of the operation warrants it. For example, in a small farm processing operation, facilities in a nearby farmhouse will suffice. Hand washing and toilet facilities do not have to be part of the changing facilities but will have to be reasonably accessible bearing in mind the scale and size of the establishment. Elbow operated taps or normal taps fitted with elbow-operated extensions are acceptable. Hand operated taps with an automatic cut off may also be acceptable.

Storage of detergents, other substances etc.

3. The requirement in paragraph 1 (i) only relates to the storage of detergents, other substances etc. that may be hazardous.

Working areas

4. Food authorities should interpret the requirement in paragraph 2 (2) for separate working areas according to the nature of the operation. In most cases physical separation e.g. by walls, partitions, pipes etc. will be possible between different materials/handling operations. However, in low risk operations including most small scale establishments separate work areas in one large room or time separation (between processes) would be acceptable.

Walls

5. The requirement in paragraph 2 (3)(b) for walls to be covered with light coloured coating should be interpreted as meaning that any colour would be acceptable provided soiling can be identified.

Washing facilities

6. The requirement in paragraph 2 (3)(g) for adequate hand washing facilities relates only to working areas (these are not required in storage or office areas). Such facilities do not need to be in working areas (depending on perceived risk) but must be readily accessible.

Part II

Mechanical filling and automatic sealing

7. In paragraph A2, the requirement for equipment for mechanical filling and automatic sealing of containers applies only in the case of heat treated drinking milk and liquid milk-based products (i.e. cream (excluding clotted cream,) drinking yoghurt etc.). It does not apply to ice-cream (or ice-cream liquid mixes). This requirement has been the reason for most applications for temporary derogations under Directive 92/47 (see paragraph 15 of the Code of Practice) and is a requirement from which a permanent derogation can be granted for limited production establishments or limited production lines (see paragraph 17 of the Code). The requirement does not apply to churns or tanks (which food authorities should interpret as including bag in the box packs) and any container with a capacity of over 4 litres.

Cooling equipment

8. Regarding paragraph A3, a record of thermometer calibration can be kept in any form e.g. written or on computer - provided that this can be made available for inspection by food authorities. Calibration will need to be checked in a manner acceptable to food authorities.

Reusable Containers

9. In paragraph A 4(b) the requirement for equipment to clean and disinfect mechanically is a new one and may be difficult particularly for some smaller establishments to comply with. Food authorities should allow such businesses time to adjust to this requirement provided that the hygiene of operations is satisfactory. In certain cases manual cleaning methods could be allowed to continue.

Standardisation Equipment

10. Food authorities should note that the requirement in paragraph A 5 for standardisation equipment and containers for storing standardised milk will only apply when an establishment produces standardised milk i.e. whole milk which has had its fat content adjusted as allowed under EC Regulation 1411/71, as amended (enforced by food authorities).

Milk purification equipment

11. Regarding paragraph A 6 and Section B and C filters or clarifiers are acceptable (as well as centrifuges) for removing impurities from milk.

Heat treatment equipment

12. The requirements in paragraph A 7(1)(a) should not be applied in the case of batch pasteurisers. Alternative heat treatment equipment is acceptable provided hygiene requirements are met and batch pasteurisers should therefore be allowed to be used as at present. Food authorities are not required to give written acceptance.

Part III

Equipment used for other products

13. [Regarding paragraph A(4) working areas, instruments and equipment could be used for work on other foodstuffs or other milk based products for non-food use at the discretion of the authorised officer.]

Disinfectants

14. Regarding paragraph A 11 food authorities should regard as acceptable disinfectants which are suitable for use with foodstuffs and used in accordance with the manufacturers' instructions [or more stringent operating instructions which achieve the same effect.]

SCHEDULE 3

RAW MILK REQUIREMENTS

Part I

Food authorities

1. As regards requirements in paragraphs 1 and 2(b) producers will be responsible for ensuring that these are met through private veterinary inspections at regular intervals (preferably every year). In Scotland food authorities will be responsible for checking records of private inspections (which producers should be encouraged to keep readily accessible) during their normal enforcement visits. If authorities suspect that requirements are not being complied with due to problems with notifiable disease they should notify the local Animal Health Office. If a notifiable disease is not suspected but a contravention of other requirements is they should notify the farmer and advise him to consult his private veterinary surgeon. (In England and Wales ADAS will undertake checks on records of private inspections).
2. As regards requirements in paragraph 2(a) (tuberculosis and brucellosis in cows and buffaloes) and paragraph 2(c) (brucellosis in goats and sheep), these will be enforced by Agricultural Departments.

Part II

Added water

3. The prime responsibility for checking for added water rests with occupiers of establishments and first purchasers (those bodies such as Milk Marque and others who buy raw milk from production holdings). However food authorities (Trading Standards Officers in County Councils and the Isles of Scilly and Trading Standards Officers (or Environmental Health Officers if appropriate) in London and Metropolitan counties and Environmental Health Departments in Scotland) will need to check records kept by occupiers or first purchasers (including those relating to individual holdings where necessary) and also undertake spot checks where necessary to ensure that water is not being added to raw milk. In the case of milk delivered from several holdings spot checks need to be carried out on the holdings. If an initial check indicates that water may have been added, food authorities will need to take an authentic sample on the holding(s) representing

the milk of one morning and/or evening's milking. If this shows that water is being added, they should consider appropriate action.

Antibiotic Residues

4. Paragraph 1(b) requires raw milk (including raw goats and sheep milk) to comply with the limits for veterinary medicinal products including antibiotics specified in Annex I and III of Council Regulation 2377/90 (as amended). The prime responsibility for testing for residues rests with occupiers of establishments/first purchasers. Food authorities (as indicated in paragraph 2 above) should note that the Commission has prepared a draft document on methods of analysis for the substances listed in that Regulation which is expected to be revised shortly. Food authorities will need to check records kept by occupiers/purchasers including those relating to individual holdings where necessary and undertake spot checks on milk as appropriate.

Other standards

5. In the case of the standards laid down in paragraph 2 [with the exception of *S.aureus*] the Regulations specify a sampling regime for the operator/purchaser. Food authorities will need to ensure that operators/purchasers are carrying out the specified sampling plan and perform random checks to satisfy themselves that the standards are being complied with. Note that paragraph 4 allows the standards to be checked either at the holding or at the treatment or processing establishment (although the Commission has proposed that standards should only be applied to the milk from one holding - a proposal which the UK is opposing.)

6. In the case of somatic cell counts (paragraph 4) each dairy/creamery or purchaser will keep records of the counts of its milk intake either:

- (i) by testing milk from each holding on a random basis, or
- (ii) from a sample representing a day's intake.
[The Directive states that there shall be at least one sample per month].

From this data the dairy/purchaser will calculate a three month geometric mean [relating to its intake]. The dairy/purchaser will take steps to ensure that the somatic cell count of the milk it received does not exceed the limits laid down and if these are exceeded it will go back to individual producers' records to see how it can segregate supplies in order to bring the average three monthly mean to acceptable levels. Records will be made available for inspection by EHOs.

NB. This system will need to be amended if the Commission proposal on application of standards mentioned in paragraph 5 is adopted.

7. Where plate count or somatic cell count standards are exceeded operators/purchasers should inform food authorities. When these standards are exceeded, food authorities should take action only if subsequent investigation indicates a potential danger to health. It would not be appropriate to take such action in a case where somatic cell count standards alone had been exceeded. This should be noted particularly in the case of small scale processors who use milk obtained from only one source rather than from a number of sources and who may therefore have more difficulty in meeting somatic cell count standards. Food authorities should also note that in accordance with Regulation 15 raw milk or products made with such raw milk with plate count or somatic cell counts that exceed those laid down can be sold on the domestic market but without an EC health mark until 31 December 1997.

8. In undertaking sampling food authorities should take account of provisions of the Food Safety (Sampling and Qualification) Regulations 1990 as well as of Code of Practice No. 7: Sampling for analysis or examination.

SCHEDULE 4

DRINKING MILK REQUIREMENTS

1. The standards laid down apply to products after wrapping and before being removed from an establishment [not at retail level]. Operators will need to carry out their own system of checks in accordance with Regulation 13 in order to demonstrate that their production meets the required standards. They will need to draw up sampling programmes bearing in mind the scale of the operation and the nature of the products being produced. Food authorities should encourage use of acceptable industry codes of practice such as those already prepared by the Dairy Trade Federation.
2. Food authorities should check records of tests carried out by operators and may also carry out random sampling/spot checks as necessary on the basis of inspection ratings as laid down in statutory Code of Practice No. 9 (Revised). Food authorities should follow the sampling plans laid down in the Schedule (i.e. n, c, m, M).
3. Food authorities should advise operators that where they encounter problems in meeting the standards, necessary remedial measures be taken without delay. If an operator experiences problems involving a possible health risk, the food authority should investigate as necessary and if there is a potential danger to health take appropriate action (if necessary in accordance with statutory Code of Practice No. 16 on the enforcement of the Food Safety Act 1990 in relation to the food hazard warning system). In the case of a failure of heat treated milk to meet the requirements for plate count at 21°C per ml after incubation, food authorities should only consider action if there has also been a failure of the requirements for coliforms.
4. Food authorities should note that the requirements in Part I paragraph 1 of the Regulations have been taken from existing cows milk legislation in England and Wales and extended to raw goats and sheep milk. The standards apply to raw cows milk sold at the farm gate or used for farmhouse catering or sold to a distributor and to raw goats and sheep milk sold to the ultimate consumer or to another outlet. ADAS will continue to enforce standards relating to raw cows drinking milk for the present. Food authorities will remain responsible for enforcement of standards relating to raw goats and sheep milk. In Scotland the sale of raw cows milk for drinking continues to be prohibited. Sale of raw goats and sheep milk is only allowed as sales from the farm gate to the ultimate consumer. The standards applying to raw goats and sheep milk are those that apply to raw cows milk in England and Wales.

5. Part III paragraph 7 would not enable milk pasteurised in one establishment to be sent for a second pasteurisation in another establishment (so called double pasteurisation) and still be called pasteurised. This procedure is common in the production of a proportion of low fat milk in the UK. We understand that the Commission are likely to accept the continuation of this practice subject to certain restrictions which we are opposing in Brussels. Food authorities should therefore allow this practice to continue as at present.

6. Regarding sampling see comments under Schedule 3.

SCHEDULE 5

REQUIREMENTS FOR MILK FOR THE MANUFACTURE OF MILK-BASED PRODUCTS

1. Food authorities should note that paragraph 1 allows temperatures and times specified for treatment of raw milk to be exceeded for "technological reasons". These reasons will include cases where higher temperatures are essential to the manufacture of certain products e.g. cheeses and also instances over a weekend for example when establishments are unable to process their milk within the specified period. Written acceptance is not required.
2. Establishments are required to keep records of data produced by recording thermometers in respect of manufacture of thermised, pasteurised and UHT milk (see Regulation 13(c) for 2 years (or 2 months in the case of products which cannot be stored at ambient temperature) and food authorities should refer to these to check that treatment of milk has been carried out correctly.

SCHEDULE 6

REQUIREMENTS FOR MILK-BASED PRODUCTS

Part I

1. As under Schedule 4, the standards apply to products after wrapping and before removal from an establishment (not at retail level). Operators will need to carry out their own system of checks in accordance with Regulation 13 to demonstrate that their production meets the required standards. They will need to draw up sampling programme bearing in mind the scale of the operation and the risk associated with the product. Food authorities should encourage use of acceptable industry codes of practice. Food authorities should check records of tests carried out by operators and may also wish to carry out spot checks as necessary on the basis of inspection ratings as laid down in Code of Practice No. 9 (Revised): Food Hygiene Inspections. Food authorities should follow the sampling plans laid down in the Schedule (i.e. n, c, m, M).
2. Where operators notify the food authorities of a withdrawal of products from the market (see Regulation 13) food authorities should discuss appropriate action with the operator. Food authorities should also consider if any action is necessary under statutory Code of Practice No. 16 (on enforcement of the Food Safety Act in relation to food hazard warning systems).
3. Food authorities should also advise operators of the following guidelines for indicator organisms which should help them in ensuring proper operation of their establishments and in carrying out checks on their products (see attached list). Food authorities should note that these are only guidelines and therefore that certain products within the categories may not meet the standards mentioned.

Part II - IV

4. Food authorities should note that these requirements have been taken from existing national legislation relating to heat treatment of cream, milk-based drinks and ice cream. They apply to any premises selling or handling cream and dairy ice cream, i.e. including retail premises such as ice cream vans.
5. Regarding sampling see comments under Schedule 3.

Indicator organisms: guidelines

Type of micro-organism	Product	Standard (ml/g)
- Coliforms 30°C	Liquid milk-based products	m = 0
		M = 5
		n = 5
		c = 2
	Butter made from pasteurised milk or cream	m = 0
		M = 10
		n = 5
		c = 2
	Soft cheese (made from heat-treated milk)	m = 10,000
		M = 100,000
		n = 5
		c = 2
	Powdered milk-based products	m = 0
		M = 10
		n = 5
		c = 2
	Frozen milk-based products (including ice-cream)	m = 10
		M = 100
		n = 5
		c = 2
- Plate count 30°C	Frozen milk-based products (including ice-cream)	m = 100,000
		M = 500,000
		n = 5
		c = 2

SCHEDULE 7

STORAGE REQUIREMENTS

1. Food authorities in England and Wales should note that paragraphs 1 and 2 relate to storage temperatures on a production holding which are part of registration conditions enforced by MAFF in England and Wales.
2. Temperatures in paragraphs 3 to 7 apply at treatment establishments. In addition the requirements at paragraphs 5 and 6 relate to storage at premises other than treatment establishments including storage/distribution depots, cash and carries, wholesalers etc. The requirement for storage temperatures to be registered could be met through records on a computer or in any other form bearing in mind the nature and scale of the operation.

SCHEDULE 8

TRANSPORT REQUIREMENTS

1. Doorstep deliveries - Food authorities should note the exemption in paragraph 2(3) from the temperature requirement for pasteurised milk intended for doorstep deliveries. This should be interpreted as applying to milk floats (or other small delivery vehicles) delivering pasteurised milk principally to households but also to corner shops or institutions e.g. schools.

Hygiene

2. Food authorities should note that the precise frequency for cleaning of tanks/containers in paragraph 3 will depend on the circumstances of the operation and its size. Food authorities may wish to undertake spot checks to ensure that adequate cleaning is taking place.

Commercial documents

3. The requirement for certain products to be accompanied by a commercial document giving specified details applies only to products in bulk. [Need to clarify this in Brussels]. It does not apply to deliveries direct to consumers. The document can be an invoice/advice note or any other document (in original or copy form). As indicated in paragraph 38 of the Code of Practice, during the period up to 1 January 1995 (expected to be extended to 1 January 1996), the health mark on a commercial document may be the only way in which to identify whether a product comes from an approved establishment and can be traded (since health marking on packaging will not be compulsory during this period). [Where a consignment is subsequently split into separate consignments, a copy of the commercial document will need to accompany each consignment].

SCHEDULE 9

WRAPPING AND PACKAGING

1. Food authorities should note that wrapping and packaging may take place in the same room as processing, as long as there is no risk of contaminating the products. In addition designated areas within the same room for wrapping, packaging and storage will be acceptable particularly in the case of small scale establishments.
2. In paragraph 3(b) the requirement for wrapping and packaging to be brought to the establishment in a protective cover would not apply in the case of returnable glass bottles brought back to an establishment on milk floats (although such bottles would need to be stored so as to prevent contamination).
3. In paragraph 3(d) automatic assembly of packaging would include on line assembly of aseptic packaging. In some small scale establishments packaging is only assembled when brought into the packaging area and food authorities should allow this to continue provided that assembly is undertaken hygienically.
4. The requirement in paragraph 3(e) that staff may not handle both packaging and unwrapped products will be difficult for small scale establishments with only a few staff. In such cases staff should be allowed to continue with both activities provided food authorities are content that sufficient precautions are being taken to prevent contamination of products.
5. In paragraph 3(f) the requirement will not apply to products which undergo further processing after packaging i.e. blast chilling/blast freezing.
6. Food authorities should note that the requirement in paragraph 4 for sealing of containers of certain products to be carried out automatically does not apply to limited production (see paragraph 17 of Code for definition).

SCHEDULE 10

LABELLING AND HEALTH MARKING

1. Directive 92/46 does not apply at retail level. It is not a requirement therefore for a product put on retail shelves to carry the labelling or health mark information. The requirement for this information to be shown applies only up to the time the product arrives at a retail outlet. The Food Labelling Regulations cover labelling at retail level.

2. Food authorities should note that Part II paragraph 2 would mean that in the case of small portions e.g. triangles of cheese in a circular box, the health mark need only be applied to the box itself. Where this product was subsequently put in further packaging e.g. a larger cardboard box the health mark would also apply to that box. We interpret reference to small packaged units to mean products of 10 sq cm or less (expected to be increased to 25 sq cm shortly) in accordance with provisions in the Food Labelling Directive 79/112. The Commission has also said that individual (e.g. impulse) ice cream for sale would not need to be health marked and the Directive is expected to be amended to reflect this.

3. In Part II paragraph 4, "UK" would be acceptable instead of United Kingdom in option (b) when a product is sold in the UK market. [We expect that it would also be acceptable where the product is exported to another Member State although this has to be clarified in Brussels]. The Commission is also expected to propose that the approval number can be placed outside the oval health mark provided there is a reference in the mark to the place where the number can be found e.g. "for approval number - see base".

4. Food authorities should note that it would be acceptable to place a health mark on any part of a product eg the base provided it is visible for inspection purposes. Health marks can be of any size provided they are legible.

SCHEDULE 11

METHODS OF ANALYSIS

1. Schedule 11 lays down the reference methods of analysis for the standards given in the Regulations. It can be seen that there are no reference methods for the peroxidase test or phosphatase test for non-bovine milks. This is because reference methods are not available. It is hoped that the Commission will elaborate methods in this area in the future. Where no reference methods have been laid down, internationally accepted methods should be used. (Industry may be using methods that they are aware of for the purposes of routine control. For example the goat industry use the modified phosphatase test as published by D J Williams in 1986. "A modification to the Aschaffenburg and Mullen Alkaline Phosphatase Test suitable for Goats Milk, Australian Journal of Dairy Technology 41, 28*").

**DRAFT GUIDELINES ON ENFORCEMENT
OF THE DAIRY PRODUCTS (HYGIENE) REGULATIONS 1994
("THE REGULATIONS") BY ADAS
DAIRY HYGIENE INSPECTORATE**

INTRODUCTION

1. These guidelines give guidance to the Dairy Hygiene Inspectorate (the Inspectorate) on the requirements of the Dairy Products (Hygiene) Regulations 1994. The Regulations, which include several Schedules, implement the requirements of Council Directive 92/46 laying down rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products from cows, sheep, goats and buffaloes intended for human consumption. They also include certain provisions from existing legislation which following review have been retained on public health grounds.
2. These guidelines explain the role of the Inspectorate in the monitoring and enforcement of the Regulations and should be read in conjunction with relevant Statutory Codes of Practice under the Food Safety Act. When more specific requirements are set down in these guidelines, these shall take precedence.
3. The Inspectorate should also follow guidance issued separately by central Government.
4. Where difficulties of interpretation arise, authorised officers should discuss these with the Team Manager and overall Inspectorate Manager. If this does not resolve the matter, the issue should be referred to MAFF Milk and Milk Products Division.
5. [Matters of Policy on the Regulations and these guidelines and significant enforcement issues will be considered by the Liaison Committee consisting of MAFF, DH and WOAD.] The Inspectorate should have regard to any advice or opinion given by that Committee.

COMPETENT AUTHORITY

6. MAFF is the central competent authority ie the central Government department with lead responsibility for these Regulations. For the purposes of enforcement at local level, the Inspectorate is the competent authority responsible for:

- (a) registration of all production holdings in England and Wales in accordance with Regulation 4;
- (b) controls on production of raw cows milk sold for drinking at farm level (see Regulation 12) and
- (c) checking plate count and coliform standards for raw cows drinking milk (see Schedule 4 Part I paragraph 1).

7. Checks on health of animals (see Schedule 3 Part I) will be dealt with mainly by MAFF local veterinary inspectors although ADAS will be responsible for checking records of private veterinary inspections. Remaining requirements including the approval of processing establishments will be the responsibility of the food authority.

8. NB. In England and Wales where a premise is both a production holding and a processing establishment, the appropriate Minister will be responsible for registering it as a production holding, and the food authority will be responsible for approval of the processing part of the premises.

9. It will be for the appropriate competent authority to establish if the premises is subject to the Regulations. In England and Wales where there is doubt relating to the location of a processing premises on the same site as a production holding, which has been registered by the Inspectorate (on behalf of MAFF), food authorities should consult their local Inspectorate office. The Inspectorate in England and Wales should liaise with food authorities in respect of processing premises which are also on a production holding in order to minimise problems for operators and should notify food authorities if they find processing taking place on production holdings. The Inspectorate should notify food authorities in cases where they suspect that any person on a production holding is suffering from an infectious disease.

SCOPE OF REGULATIONS

10. The Regulations cover premises engaged in
- a. production of raw milk (production holdings);
 - b. heat-treatment of milk (treatment establishments); and
 - c. manufacturing, preparing, processing, (including slicing, packaging, bottling, wrapping or re-wrapping) of any dairy products (processing establishments).

In addition, storage depots and wholesalers etc are subject to certain storage and transport provisions. Certain retail premises selling dairy products are exempt (see paragraph 11 below).

Exemptions

11. Premises which are producing or handling dairy products solely for their own consumption, or are supplying other than in the course of a business, are exempt from all provisions in the Regulations. There are also exemptions relating to certain catering and retail premises involved in processing of milk and production of milk-based products. Any queries in this area should be referred to food authorities.

Processor/retailers of raw milk/raw milk products

12. There is some discretion in the Directive for Member States to set their own rules for sales of raw milk or raw milk-based products made direct by producers to consumers. Ministers have now agreed that on-farm processors of raw drinking milk (ie those wrapping/bottling raw milk) or raw milk-based products produced on the farm premises who sell their entire output of such products direct to the ultimate consumer should be exempt from approval (although they will need to meet general hygiene requirements for processing establishments in Schedule 2 Part III of the Regulations and requirements relating to duties of occupiers in Regulation 13). In addition existing restrictions on sales of raw cows drinking milk will continue as provided for in Regulation 12. The Inspectorate will be responsible for enforcing these restrictions at farm level. Food authorities will be responsible for enforcement of provisions relating to sales by distributors.

APPLICATIONS AND REGISTRATION OF PREMISES

13. Separate guidelines have already been issued to the Inspectorate relating to registration of production holdings prior to the coming into force of the Dairy Products (Hygiene) Regulations. After that date the following details will apply.

Applications

14. Responsibility for applying for registration rests with the occupier. Applications must be made on the appropriate form (MDR 890) to the Inspectorate. The Inspectorate should ensure that at the earliest opportunity they discuss with potential applicants the requirements of the Regulations and the timing of applications.

Registration

15. The Inspectorate should deal promptly with any producer seeking registration. Where the Inspectorate is satisfied that the production holding meets the relevant requirements of the Regulations it should notify the applicant in writing of its decision. It shall allocate to each a unique identification reference which shall be known as the registration number.

16. Registration is subject to continuing compliance with the Regulations and the Inspectorate will wish to draw this to an operator's attention when granting registration. Whilst the responsibility for informing the Inspectorate of any significant alterations to methods of operations, premises or equipment (other than by way of maintenance or repair) remains with the operator, the Inspectorate should maintain links with occupiers of registered production holdings to facilitate communication of such information.

17. Where registration is refused the Inspectorate must notify the applicant in writing of the reasons and the actions necessary to comply with the relevant requirements of the Regulations.

RIGHT OF APPEAL

18. Producers have the right of appeal to Magistrates if registration has been refused. The Inspectorate should make producers aware of their right of appeal. Wherever possible

they should deal promptly with any proposal by a producer where this would avoid the need for a formal appeal.

RETURNS TO CENTRAL GOVERNMENT

19. The Inspectorate in England and Wales will maintain a central list of all registered production holdings and keep these up to date so they can be immediately available to MAFF as required.

Approach to Inspection

20. Before authorising an officer to carry out inspections of production holdings the Inspectorate should be satisfied that the officer is competent to do so, suitably qualified and possesses the necessary experience which would allow him/her to undertake the duties.

21. The Inspectorate should ensure that officers authorised to carry out inspections of production holdings or undertake enforcement activities under the Regulations are fully aware of the content of the Regulations and these guidelines and continue to receive appropriate training. The Inspectorate should also ensure that these officers are aware of the content of relevant Codes of Practice under the Food Safety Act 1990.

Frequency

22. In deciding the frequency and approach to inspections, the Inspectorate should have regard to Code of Practice No 9: Food Hygiene Inspections (Revised) particularly regarding inspection ratings.

Reports

23. On completion of the inspection, the officer should discuss with the occupier or his representative a summary of the matters which in the opinion of the officer breach the requirements of the Regulations and any advice on good hygiene practice he/she may need to give. The officer should submit a [written] report in accordance with Code of Practice No.9: Food Hygiene Inspections (Revised).

Enforcement Action

24. The Inspectorate has a range of options available when breaches of the Regulations are identified during an inspection. Advice on the enforcement action possible is contained within Codes of Practice No 5: The Use of Improvement Notices and No 6: Prohibition Procedures. In deciding what action should be taken when breaches of Regulations are identified, the officer should have regard to advice contained in other relevant Codes of Practice. The Inspectorate must clearly distinguish between recommendations which might be appropriate on the basis of good manufacturing practice and those considered necessary to satisfy the requirements of the Regulations.

Monitoring the Quality of Inspection

25. The Inspectorate should ensure that documented procedures which exist within the Inspectorate to monitor the quality and nature of inspections undertaken by their officers incorporate the requirements of the Dairy Product (Hygiene) Regulations, the guidance in this document and other guidance issued separately by MAFF.

Schedules

24. Guidance on aspects of certain Schedules to the Regulations is set out in the Annex attached.

SCHEDULE 1

GENERAL CONDITIONS OF HYGIENE FOR PRODUCTION HOLDINGS

Part IAnimal Identification

1. In paragraph A1 the requirement applies to both milking and dry stock. Females close to parturition should also be kept in accordance with this requirement.

Milking Equipment Storage

2. In paragraph A3 there would be an exception for animals kept in stalls and milked directly into a milk line which was fitted permanently in that building. (For example a cowshed fitted with a milk pipeline.)

Pigs and Poultry

3. In paragraph A4 some large open span buildings where pigs are housed at one end and milking animals at the other may be permitted providing no smell or contamination reaches the milking area.

Vermin Control

4. In paragraph A6 it should be noted that this also applies to infestation in adjacent buildings, feed stores etc. Appropriate measures should be in place to prevent birds from entering milking areas and milk rooms even if it requires modifications to buildings.

Clean Clothes

5. In paragraph B1(a) although recommended, they need not be waterproof as long as they are clean.

Illness

6. In paragraph B3 there is no requirement for annual medical certification to confirm this point.

Part II

Conditions for housing of animals

Design and construction

7. In paragraph 1 evidence of dirty animals, inadequate bedding, stale or foul air, overcrowding or physical damage such as swollen hocks would be regarded as unsatisfactory.

Bedding

8. In paragraph 2 in practice it would be difficult to achieve a satisfactory standard of animal cleanliness unless some bedding is used.

Disinfectants

9. In paragraph 3 outhouses refers to feed stores or isolation premises. Strong smelling or phenolic disinfectant liable to contaminate milk should not be used. (Generally disinfectants should be regarded as acceptable provided they are suitable for use with foodstuffs and are used in accordance with the manufacturer's instructions).

Part III

Structure of the premises

10. In paragraph A1(a) there should be no direct access between the milk storage room and animal housing.

Walls and flooring

11. In paragraph A1(b) normally good quality concrete for floors and good quality cement rendering on walls will be adequate. However in some areas painting cement rendering with a durable waterproof paint or fitting impervious sheeting may be required. Tiles or plastic sheeting can be satisfactory if properly installed and maintained. Wooden materials should be avoided but if they are fitted must be painted or sheeted to facilitate cleaning.

Ventilation and Lighting

12. In paragraph A1(d) natural lighting should be provided if at all possible and supplemented by sealed unit fluorescent strip lights if possible. Air bricks in external walls and/or mechanical ventilation may be necessary to avoid excessive condensation.

Water supply

13. In paragraph A1(e) if water other than mains is used within the milking premises it is most important that there is no risk of contamination of the milk by the splashing of equipment by such water. Only potable water should be available in the milk room. If there is concern about the standard of water being used, this should be reported to the local food authority.

Equipment cleaning

14. In paragraph B3 the requirement to rinse with potable water does not apply where the disinfectant is specifically designed not to be rinsed off after application, nor does it apply where disinfection is by steam. Adequate supplies of heated water should also be available.

Moveable Bails

15. In paragraph C2c this means frequent moves to a fresh area of pasture but in wet conditions this could be every day to avoid accumulations of mud and dung occurring.

Feed Storage

16. In paragraph D1 this should not prohibit the use of a feed loft above the milking area. However, the use of any type of feed which creates a dusty atmosphere in the premises during milking should be prohibited.



Part IV

Milking Conditions

17. In paragraph 1 the feeding of dusty or strong smelling feeds, the use of dusty bedding materials close to the milking premises, and application of certain chemicals to animals might have an adverse effect.

Udder Diseases

18. In respect of paragraph 4 whilst milking diseased animals last is often good practice it may not always be practicable on all farms and so it will be necessary in many instances for separate milking equipment to be available to milk animals with udder disease during milking.

Teat dips

19. Regarding paragraph 5, in most cases teat dips/sprays will have been licensed by the Veterinary Medicines Directorate (VMD) under the Medicines Act. The Inspectorate should be able to tell from the manufacturer's instructions whether the dips/spray could be safely used before milking.

SCHEDULE 3

RAW MILK REQUIREMENTS

Part I

1. As regards requirements in paragraph 1 and 2(b) producers will be responsible for ensuring that these are met through private veterinary inspections at regular intervals (preferably every year). The Inspectorate will be responsible for checking records of private inspections (which producers should be encouraged to keep readily accessible) during their normal enforcement visits. If the Inspectorate suspects that requirements are not being complied with due to problems with notifiable disease it should notify the local Animal Health Office. If a notifiable disease is not suspected but a contravention of other requirements is, the Inspectorate should notify the farmer and advise him to consult his private veterinary surgeon.

2. As regards requirements in paragraph 2(a) (tuberculosis and brucellosis in cows and buffaloes) MAFF Local Veterinary Inspectors or Veterinary Officers will carry out tuberculin tests on herds in accordance with Animal Health legislation. (They will also carry out a visual examination of animals tested and a physical examination of animals to which suspicion of TB attaches.) Purchasers of raw cows milk (eg Milk Marque) are expected to be responsible for collecting samples of milk and sending them to GENUS (and possibly other specified laboratories) for testing for brucella under Animal Health legislation. Producer retailers of cows milk will continue to have bulk milk samples taken by SVS staff.

3. As regards requirements in paragraph 2(c) (brucellosis in sheep and goats) all UK flocks/herds are currently regarded as being officially brucellosis free. However sample surveys of sheep and goats will continue to be undertaken by Local Veterinary Inspectors to check on this.

Parts II and III

4. These will be enforced by food authorities.

SCHEDULE 4

DRINKING MILK REQUIREMENTS

Part I

1. Regarding paragraph 1, the Inspectorate will continue to be responsible for testing for plate count and coliform standards in relation to raw cows drinking milk for the time being. A sample of raw milk can be taken from the bulk milk tank before milk is bottled. Sampling provisions are contained in the Food Safety (Sampling and Qualifications) Regulations 1990 and Code of Practice No.7: Sampling for analysis or examination. Schedule 11 indicates the reference methods for analysis of raw milk.
2. Remaining provisions in the Schedule are to be enforced by food authorities.

SCHEDULE 7

STORAGE REQUIREMENTS

1. Requirements in paragraphs 1 and 2 are part of registration conditions enforced by the Inspectorate.
2. It should be noted that temperatures in paragraph 2 can be exceeded in some cases for technical reasons. Authorisation in writing is not required. However the Inspectorate will need to liaise with the relevant food authority in cases where a derogation from temperature requirements is sought since food authorities are responsible for standards relating to manufacture of products.
3. Remaining provisions in the Schedule will be enforced by food authorities.

contents

SECTION 1	INTRODUCTION	2
SECTION 2	THE REGULATIONS	3
SECTION 3	REQUIREMENTS FOR PRODUCTION HOLDINGS	4
	♦ Premises	
	♦ Animal health	
	♦ Raw milk standards	
	♦ Hygiene requirements for personnel	
SECTION 4	ENFORCEMENT AND PENALTIES	7
SECTION 5	FURTHER INFORMATION	8

SECTION

1

introduction

In June 1992 the EC Council of Ministers adopted Directive 92/46, which lays down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products. Throughout the UK the Directive will be implemented in new national hygiene Regulations.

They are:

The Dairy Products (Hygiene) Regulations 1994

(which will apply in England and Wales)

The Dairy Products (Hygiene) (Scotland) Regulations 1994

The Dairy Products (Hygiene) Regulations

(Northern Ireland) 1994

The new Regulations are expected to come into operation during 1994, and will replace most of the existing milk and dairies' hygiene legislation presently in force in each part of the UK.

This leaflet, which has no statutory force, is intended only as a brief guide for dairy farmers to the main provisions concerning milk production in the new Regulations. While the guide may serve as a convenient summary, it should not be regarded as a definitive statement of the law as contained in the Regulations and reference should also be made to these once they are in force.

the regulations

The Regulations will apply to milk intended for human consumption produced from cows, sheep, goats and buffaloes and sold or supplied in the form either of milk or milk-based products.

All premises where milk is produced will be referred to as '**production holdings**'. In England and Wales premises will need to be registered and, in Scotland and in Northern Ireland, they will need to be licensed. It is expected that those dairy cow farms currently registered/licensed under existing legislation (i.e. the Milk and Dairies (General) Regulations 1959, the Milk and Dairies (Scotland) Regulations 1990, and the Milk Regulations (NI) 1987) will automatically be regarded as registered/licensed under the new Regulations. Production holdings where milk is produced from sheep, goats and buffaloes will need to be registered/licensed under the new Regulations.

All premises where milk undergoes some form of heat treatment or processing, such as pasteurisation, product manufacture, packing (including bottling), will be known as '**dairy establishments**'. Such premises, which may be located on the same site as a production holding, will be subject to additional requirements to those applying to production holdings. A separate booklet entitled 'A Guide for Dairy Product Processors to the Requirements of the EC Directives on Milk Hygiene (EC Directives 92/46 and 92/47)' explains these requirements and is available on request (see Section 5).

SECTION 2

requirements for production holdings

Premises

- Premises in which animals are housed or milked, or in which milk is handled or stored will need to be designed, situated, constructed, fitted and equipped, maintained and managed in such a way as to ensure that conditions are hygienic. Dairy cow farms which meet current standards set out in existing legislation are unlikely to have difficulty in meeting the new standards.
- Suitable means for effective isolation or separation of animals which are infected or suspected of being infected with any of the diseases referred to in the 'Animal health' part of this section below will be necessary.
- Pigs and poultry will not generally be allowed to be housed in premises where milking animals are housed or milked.
- Animals of all species shall be kept away from premises and sites where milk is stored, handled or cooled.
- Adequate measures will be required to control flies, rodents and other vermin, mainly in those areas where animals are milked and where milk is stored.
- A sufficient supply of potable water will be required. Non-potable water will be allowed for cleaning surfaces (such as yards) which do not come into contact with milk.
- The storage of those feeding stuffs which have an adverse effect on milk will not be allowed in premises where animals are milked or where milk is handled or stored.

SECTION 3

Animal health

- Cows' and buffaloes' milk will have to come from herds which are officially tuberculosis-free and either brucellosis-free or officially brucellosis-free.
- Goats' and sheeps' milk will have to come from production holdings which are either brucellosis-free or officially brucellosis-free (that is free of *Brucella melitensis*).
- Milk from healthy animals which does not meet the two requirements set out above can only be used for the manufacture of heat-treated milk or heat-treated milk-based products.
- Cows' milk will have to come from cows yielding at least two litres of milk per day. Animals with clinical udder diseases will have to be milked after animals which do not have such diseases, or by a separate machine or hand stripped, and the milk will have to be discarded.
- Milk will not be allowed to be used for human consumption if it comes from animals which:
 - show symptoms of infectious diseases communicable to humans;
 - have any visible disorder impairing their general state of health or which are suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever or a recognisable inflammation of the udder;
 - have any udder wound likely to affect the milk;

- have had substances having a hormonal action or thyrostatic action (i.e. a substance with a depressant effect on thyroid activity and thyroid hormone production) administered illegally;
- have been treated with substances which pose a risk to human health, such as antibiotics for mastitis control, unless official withdrawal times have been observed.

Raw milk standards

- Residues such as antibiotics and pesticides will not be allowed to exceed the levels specified in legislation.
- Water must not be added to raw milk.
- Standards will be laid down for the total bacterial count in milk from all species.
- A standard for somatic cell count is set for cows' milk and buffaloes' milk only, although a standard for goats' and sheep's milk may be specified in legislation at a later date. (Somatic cells are cells in the milk which originate from the animal and generally a high somatic cell count indicates that the udder is inflamed).
- Raw milk which is not to be pasteurised before being used in the manufacture of a milk-based product will have to meet a standard for *Staphylococcus aureus*. This will apply to milk from all species.

Hygiene requirements for personnel

- High standards of personal cleanliness will be required.
- Persons who may be liable to contaminate raw milk will not be permitted to milk animals or to handle raw milk.

enforcement & penalties

Responsibility for compliance with the Regulations will rest with the producer. However, regular official inspections will be made to check for compliance. As at present, producers will usually be given reasonable time limits to make any necessary improvements.

Failure to comply with the requirements may lead to cancellation/revocation of the production holding's registration/licence and/or to the occupier of the production holding being liable to a fine or term of imprisonment or both.

An appeals procedure will be available to producers wishing to question the decision of the enforcement authority.

SECTION 4

further information

England & Wales

For further information about the requirements of the Regulations relating to production holdings in England and Wales, please contact your local ADAS Dairy Officer (where known) or your nearest ADAS Regional Dairy Officer:

South West and Wales - Clive Cook

Telephone: Taunton (0823) 337922

East and South East - Russell Brown

Telephone: Nottingham (0602) 425255

North, Midlands and West - Ian Brown

Telephone: Leeds (0532) 611222

For further information about other requirements in the Regulations in England and Wales please contact your local Environmental Health Department.

Additional information is also available by contacting:

The Ministry of Agriculture, Fisheries and Food

Milk and Milk Products Division

Room 519, Whitehall Place (East)

London SW1A 2HH

Telephone: 071 270 8243

The Welsh Office Agriculture Department

Cathays Park

Cardiff CF1 3NQ

Telephone: 0222 823624

Copies of this leaflet are available in Welsh from the above address.

SECTION

5

Scotland

For further information please contact:

The Scottish Office
Agriculture and Fisheries Department
Division A1
Pentland House
47 Robb's Loan
Edinburgh EH14 1TY
Telephone: 031 244 6411

Northern Ireland

For further information please contact:

The Department of Agriculture for Northern Ireland
Milk and Milk Products Quality Assurance Division
Dundonald House
Upper Newtownards Road
Belfast BT4 3SB
Telephone: 0232 524685

Free copies of the booklet entitled 'A Guide for Dairy Product Processors to the Requirements of the EC Directives on Milk Hygiene (EC Directives 92/46 and 92/47), outlining requirements for dairy establishments, may be obtained by writing to one of the Agriculture Departments indicated above

Further free copies of this leaflet may be obtained by writing to:

MAFF Publications
London SE99 7TP

DRAFT

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milk
HYGIENE

**A SHORT GUIDE FOR FARMERS PRODUCING AND PROCESSING MILK FROM
GOATS AND SHEEP
TO THE REQUIREMENTS OF THE EC DIRECTIVE ON MILK HYGIENE**

(EC DIRECTIVE 92/46)

July 1994

CONTENTS

SECTION 1	INTRODUCTION
SECTION 2	THE REGULATIONS
SECTION 3	REQUIREMENTS FOR PRODUCTION HOLDINGS • Premises and Equipment • Animal Health • Raw Milk Standards • Hygiene Requirements for Personnel
SECTION 4	ON FARM PROCESSING • Premises • Equipment • Hygiene • Staff • Raw milk Processing and Finished Product Standards • Wrapping and Packaging • Health Mark and Labelling • Storage and Transport • Commercial Documents
SECTION 5	ENFORCEMENT AND PENALTIES
SECTION 6	FURTHER INFORMATION

SECTION 1 - INTRODUCTION

In June 1992 the EC Council of Ministers adopted Directive 92/46, which lays down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products. Throughout the UK the Directive will be implemented in new national hygiene Regulations. They are:

The Dairy Products (Hygiene) Regulations 1994 (which will apply in England and Wales)

The Dairy Products (Hygiene) (Scotland) Regulations 1994

The Dairy Products (Hygiene) (Northern Ireland) Regulations 1994

The new Regulations are expected to come into operation towards the end of 1994, and will replace most of the existing milk and dairies hygiene legislation which is currently applied to the production of cows milk in each part of the UK.

These new Regulations will also specifically apply to the production and processing of the milk from goats and sheep which is currently subject to the more general requirements of the food hygiene regulations.

This leaflet, which has no statutory force, is intended only as a brief guide for goat's and sheep's milk producers and processors to the main provisions concerning milk and milk product production in the new Regulations. While the guide may serve as a convenient summary, it should not be regarded as a definitive statement of the law as contained in the Regulations and reference should also be made to these once they are in force.

SECTION 2 - THE REGULATIONS

The Regulations will apply to milk intended for human consumption produced from cows, goats, sheep and buffaloes and sold or supplied in the form either of milk or milk-based products.

All farms or small holdings where milk is produced will be referred to as '**production holdings**' and will need to be registered (in England and Wales) or licensed (Scotland and Northern Ireland).

All premises where milk undergoes some form of treatment or processing, such as pasteurisation, product manufacture, packing (including bottling), will be known as '**dairy establishments**'. Such premises, which may be "on farm" will be subject to additional requirements to those applying to production holdings. The main provisions relating to small scale on farm processing are summarised

in Section 4 of this leaflet but there is a separate booklet entitled "A Guide for Dairy Product Processors to the Requirements of the EC Directives on Milk Hygiene (EC Directives 92/46 and 92/47)" which explains these requirements in more detail and is available on request (see Section 6).

In England and Wales, production holdings will be inspected and registered by ADAS whereas dairy establishments will be inspected and approved by local environmental health departments. (In Scotland and Northern Ireland local Environmental Health Departments will also be responsible for inspection and licensing of production holdings).

SECTION 3 - REQUIREMENTS FOR PRODUCTION HOLDINGS

This section gives details of some of the standards required. The aim is to have premises which are well designed and easy to clean. Precautions must be taken to minimise any risks of milk being contaminated from any source, for example, by livestock, vermin or poor water supply.

Premises and equipment

- Premises in which animals are housed or milked, or in which milk is handled or stored will need to be designed, situated, constructed, fitted and equipped, maintained and managed in such a way as to ensure that conditions are hygienic. Goat and sheep production holdings which follow the recommendations contained in the relevant MAFF/DANI/DAFS Codes of Practice on the hygienic production of goats and sheep milk are unlikely to have difficulty in meeting the new standards.
- Housing, milking and milk storage/dairy areas will have to be adequately separated. There should be no direct access between housing areas and the dairy.
- The design and construction of milking areas should allow easy cleaning and thorough disinfection. In most areas concrete floors and cement rendered walls will be adequate. A good drainage and waste disposal system will be required.
- Unless milk is processed or collected from the holding within two hours of production it must be cooled to 8°C if collected/processed daily or 6°C if kept for more than one day.
- Suitable means for effective isolation or separation of animals which are infected or suspected of being infected with any of the diseases referred to in the 'Animal Health' part of this section below will be necessary.
- Pigs and poultry will not generally be allowed to be housed in premises where milking animals are housed or milked.
- Animals of all species shall be kept away from premises and sites where milk is stored, handled or cooled.
- Adequate measures will be required to control flies, rodents and other vermin, mainly in those areas where animals are milked and where milk is stored.

- A sufficient supply of potable water will be required. Non-potable water will be allowed for cleaning surfaces (such as yards) which do not come into contact with milk.
- The storage of those feeding stuffs which have an adverse effect on milk will not be allowed in premises where animals are milked or where milk is handled or stored.

Animal Health

This section outlines the animal health requirements. The aim is to ensure that milk is only obtained from healthy animals.

- Goats' and sheep's milk will have to come from production holdings which are either brucellosis-free or officially brucellosis-free (that is free of *Brucella melitensis*). The UK is officially free from brucella melitensis but local veterinary officers will undertake sample surveys periodically to check that this is still the case.

Milk from healthy animals which does not meet the requirements set out above can only be used for the manufacture of heat-treated milk or heat-treated milk-based products on the production holding.

- Animals with clinical udder diseases will have to be milked after animals which do not have such diseases, or by a separate machine or hand stripped, and the milk will have to be discarded.
- Milk will not be allowed to be used for human consumption if it comes from animals which:
 - show symptoms of infectious diseases communicable to humans;
 - have any visible disorder impairing their general state of health or which are suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever or a recognisable inflammation of the udder.
 - have any udder wound likely to affect the milk;
 - have had substances having a hormonal or thyrostatic action (i.e. a substance with a depressant effect on thyroid activity and thyroid hormone production) administered illegally;

- have been treated with substances which pose a risk to human health, such as antibiotics for mastitis control, unless official withdrawal times have been observed.

Raw Milk Standards

This section outlines the bacteriological and chemical standards required. The aim is to ensure milk is of good wholesome quality.

- Residues such as antibiotics and pesticides will not be allowed to exceed the levels specified in legislation.
- Water must not be added to raw milk.
- Standards will be laid down for the total bacterial count in milk from all species.
- Standards for somatic cell count of milk from goats and sheep may be specified in legislation at a later date. (Somatic cells are cells in the milk which originate from the animal and generally a high somatic cell count indicates that the udder is inflamed).
- Raw milk which is not to be pasteurised before being used in the manufacture of a milk-based product will have to meet a standard for *Staphylococcus aureus*. This will apply to milk from all species.
- Some testing either by the processor (or the producer) will be required to ensure that standards are being met and in support of risk analysis procedures. Advice should be sought from enforcement officers on what is appropriate for individual holdings.

In Scotland sale of raw goats and sheep milk is allowed only from the farm gate directly to the ultimate consumer.

Hygiene Requirements For Personnel

This section outlines the requirements for all people involved in milking or dairy work. They must have clean clothes and hands and be in good health.

High standards of personal cleanliness will be required.

Persons who may be liable to contaminate raw milk (through illness or infection) will not be permitted to milk animals or to handle raw milk.

SECTION 4: REQUIREMENTS FOR ON FARM MILK PROCESSING

This section sets out the additional requirements for farms which process milk or produce milk products. The aim is to ensure milk is processed safely in hygienic conditions.

Farm premises processing milk or milk products will need to be inspected and issued with an approval number to enable the use of an EC health mark on their product.

Some establishments may be exempted from certain requirements of the regulations, as follows:

- Temporary derogations are available until 1 January 1998 from the requirement to meet certain plate count standards and undertake plate count tests every 2 months. Around 500 establishments (including cows milk processors) are also entitled to temporary derogations from equipment or structural requirements but the deadline for these applications has passed and those eligible for this type of temporary derogation will be notified. (The EC health mark cannot be used on drinking milk and milk products by establishments operating under temporary derogations and the products concerned may not be exported.)
- Permanent derogations are available from many structural and equipment requirements for establishments which process no more than 300,000 litres of milk (or milk equivalent) per year into milk-based products. (A derogation in respect of mechanical filling and automatic sealing is also expected to be available for establishments or production lines processing no more than 300,000 litres of milk per year into heat-treated drinking milk (or into liquid milk-based products).
- Cheese manufacturers making long keeping cheeses may be exempted from additional requirements including wrapping/packaging requirements and some raw milk standards.
- Small establishments selling only raw milk or raw milk products direct to the consumer are exempt from approval, although they will be required to meet the general hygiene conditions in Schedule 2, Part III of the Regulations.

All dairy establishments will have to agree a risk analysis programme with their enforcement officer.

Premises

- Premises in which milk is handled or stored will need to be designed, situated, constructed, equipped and fitted, maintained and managed in such a way as to ensure that conditions are hygienic.
- Working areas should be separate from animal housing or milking areas and of sufficient size to enable work to be carried out under hygienic conditions.
- In working areas there should be well drained solid waterproof flooring which is easy to clean and disinfect; smooth easily cleanable walls, doors, and, above areas where raw materials or products are exposed, easily cleanable ceilings or roof linings.
- Adequate light and ventilation.
- Adequate supplies of hot and cold potable water for cleaning of equipment, premises and hands. Hand washing facilities must be separate from those used for cleaning of utensils and non- hand-operable taps and a hygienic means of drying hands such as disposable paper towels must be used.
- Flies, rodents and other vermin will need to be controlled on the holding and excluded from the working area.
- Storage areas must generally meet the same hygiene standards as working areas. In freezing rooms easy to clean waterproof/rot proof flooring will be necessary.
- An area for changing clothes and toilet facilities must be available. However this may be in the farmhouse if it is adjacent.

Equipment

- All equipment in direct contact with raw materials or products should be of corrosion resistant material and be easy to clean and disinfect.
- Pasteurisation may be either by high temperature short time (HTST) or batch pasteurisation. A recording thermometer (thermograph) will be required. HTST pasteurisers will require an adequate flow diversion system to prevent insufficient heating and possibly a verification system to show its operation.

Hygiene

- All equipment and instruments must be kept clean and in good condition, in order to stop contamination of raw materials or products.
- Chemicals, cleaning materials, rodenticides, animal drug treatments etc must be stored in a lockable cupboard or room and not be kept in the dairy.

Staff

- A high standard of cleanliness is required of all staff.
- Suitable working clothes and head gear must be worn which are not worn for other farm duties.
- Staff working with raw materials or products must wash their hands at least each time work is resumed and/or when contamination has occurred.
- Any wounds to the skin must be covered with a waterproof dressing.
- Staff should not smoke, spit, eat or drink in the work or storage areas.

Drinking Milk and Milk Product Standards

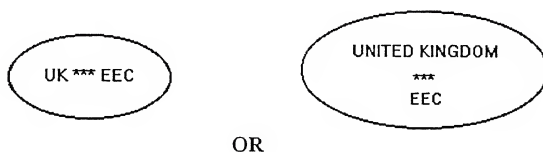
- Raw drinking milk will have to meet plate count and coliform standards.
- Heat-treated drinking milk will also have to meet standards for plate count and coliforms and pathogenic microorganisms as well as being free of antibiotic residues.
- Milk-based products will be subject to a variety of standards eg *Listeria monocytogenes* and *Staphylococcus aureus*.
- Processors will have to carry out sampling in order to show that their products meet the standards.
- Time/temperature parameters will be laid down for the production of pasteurised and sterilised milk.

Wrapping and Packaging

- Packaging will have to be stored in a hygienic place free from dust or vermin.
- Wrapping and packaging material must be strong enough to protect products effectively from physical damage and contamination
- Wrapping and packaging operations must take place under hygiene conditions (this can take place in the same room providing the room is sufficiently large to prevent contamination and staff handle the products hygienically).
- Sealing of heat-treated milk and liquid milk-based products must take place immediately after filling and with a sealing device which is tamper evident.

Health Marking and Labelling

- All products covered by the Directive and originating from approved dairy establishments must carry a health mark from 1 January 1995 (expected to be extended to 1 January 1996) except where temporary derogations apply. Such markings should be visible, legible, indelible and easily distinguishable.
- If a product is individually wrapped and subsequently packaged (eg a box of individually wrapped cheese portions) the health mark need only be applied to the packaging.
- The health mark must appear in one of the following forms within an oval surround:



*** = (for example) AA001M. The M is optional subject to the agreement of the approving authority.

(The United Kingdom can be abbreviated to UK when a product is sold on the UK market [awaiting Brussels agreement for other Member States]).

The Commission has proposed some flexibility in health marking requirements which will allow the approval number to be printed outside the oval EC health mark.

- For the purpose of checks by enforcement officers, heat-treated drinking milk and liquid milk-based products must also indicate the type and date of the last heat-treatment and where appropriate be labelled with 'raw milk' or 'made with raw milk' and a use-by date.

Storage and Transport

- Milk and milk-based products must be stored at temperatures established by manufacturers to ensure their durability.

- Pasteurised milk, except when delivered to consumers doorsteps or to small retail outlets by vehicles, must not exceed a temperature of 6°C (although on deliveries to retail businesses 8°C applies).
- Tanks, churns and containers used to transport pasteurised milk must be designed, cleaned and sealed in such a way as to allow milk to be transported hygienically.
- Other foodstuffs or products must not be transported in milk tankers if this could lead to the milk deteriorating.

Commercial Documents

- All milk products except raw milk and doorstep deliveries must be accompanied by a commercial document (eg a sales advice, invoice note) or a copy of one showing the approval number or EC health mark of the last processing establishment and indicating the nature of the heat treatment and supervising competent authority (eg District Council).
- The consignee ie person receiving consignments of milk/milk products must keep these documents for one year.

SECTION 5 - ENFORCEMENT AND PENALTIES

Responsibility for compliance with the Regulations will rest with the producer or processor. However, regular official inspections will be made to check for compliance. As at present, producers and processors will usually be given reasonable time limits to make any necessary improvements and advice on what steps are required to achieve an adequate standard.

Failure to comply with the requirements may lead to cancellation/revocation of the production holding's registration/licence or dairy establishment's approval and/or to the occupier of the production holding/dairy establishment being liable to a fine or term of imprisonment or both.

An appeals procedure will be available to producers or processors wishing to question the decision of the enforcement authority.

SECTION 6 - FURTHER INFORMATION

England and Wales

For further information about the requirements of the Regulations relating to production holdings (except raw milk standards) in England and Wales, please contact your local ADAS Dairy Officer (where known) or your nearest ADAS Regional Dairy Officer:

South West and Wales - Clive Cook

Telephone: Taunton (0823) 337922

East and South East - Russell Brown

Telephone: Nottingham (0602) 425255

North, Midlands and West - Ian Brown

Telephone: Leeds (0532) 611222

For further information about other requirements in the Regulations in England and Wales please contact your local Environmental Health Department.

Additional information is also available by contacting:

The Ministry of Agriculture, Fisheries and Food
Milk and Milk Products Division
Room 519, Whitehall Place (East)
London SW1A 2HH
Telephone: 071 270 8243

The Welsh Office Agriculture Department
Cathays Park
Cardiff
CF1 3NQ
Telephone: 0222 823624

Copies of this leaflet are available in Welsh from the above address.

Scotland

For further information please contact:

The Scottish Office Agriculture and Fisheries Department
Division A1, Room 356
Pentland House
47 Robb's Loan
Edinburgh EH14 1TY
Telephone: 031 244 6411

Northern Ireland

For further information please contact:

The Department of Agriculture for Northern Ireland
Milk and Milk Products Quality Assurance Division
Dundonald House
Upper Newtownards Road
Belfast BT4 3SB
Telephone: 0232 524685

Free copies of the booklet entitled "A Guide for Dairy Product Processors to the Requirements of the EC Directives on Milk Hygiene(EC Directives 92/46 and 92/47)", outlining requirements for dairy establishments, may be obtained by writing to one of the Agriculture Departments indicated above.

Further free copies of this leaflet may be obtained by writing to:

MAFF Publications
London SE99 7TP

DRAFT

MAFF LOGO

milk
HYGIENE

**A GUIDE FOR DAIRY PRODUCT PROCESSORS TO THE
REQUIREMENTS OF THE EC DIRECTIVES ON MILK HYGIENE**

(EC DIRECTIVES 92/46 AND 92/47)

July 1994

CONTENTS

This booklet contains the following information

Section 1

General advice and information

Section 2

Registration, licensing and approval of dairy premises

Section 3

Conditions to be met on production holdings (dairy farms)

Section 4

Conditions to be met by dairy processors (approved establishments)

Section 5

Standards (hygiene and manufacturing) for raw milk, heat-treated milk and milk-based products

Section 6

Rules on wrapping, packaging, health marking, labelling, storage, transport and documentation

Section 7

Health checks/inspections/training

Section 8

Derogations

Section 9

Further information

SECTION 1

GENERAL ADVICE AND INFORMATION

INTRODUCTION

1. This booklet provides guidance on Council Directive 92/46/EEC of 16 June 1992 (hereafter referred to as "the Directive") laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products. It also contains details (at Section 8) on Council Directive 92/47/EEC of 16 June 1992 which permits the granting of temporary and limited derogations from some of the rules contained in Directive 92/46.
2. This booklet is intended only as a guide to the requirements of Directives 92/46 and 92/47.
3. The information included in this booklet is not comprehensive, as there are many types of premises in the UK which manufacture a large range of products. Some of these will need particular advice in order to comply with the requirements of the Directive appropriate to the circumstances and type of manufacturing. Because of this, owners/managers/operators of dairies on farms or of processing establishments are advised to keep closely in touch with their local enforcement authority.
4. Directive 92/46 replaces the existing harmonised rules on health and animal health problems affecting intra-Community trade in heat treated cows milk (Directive 85/397/EEC of 5 August 1985). It also provides, for the first time, harmonised rules in the raw milk and milk products sector and covers not just cows milk but also goats, sheep and buffaloes milk.
5. As with all EC Directives, in order to implement the requirements of Directive 92/46 into UK law it is necessary to introduce implementing regulations. Since the Directive was agreed an inter-departmental working group has been preparing new Dairy Products (Hygiene) Regulations on which the dairy industry are being asked to comment. Once the consultation exercise is completed the regulations are expected to be finalised for introduction into UK law towards the end of 1994. Separate versions of these regulations will apply in England/Wales, Scotland and Northern Ireland respectively. The implementation exercise has also been used to carry out a general review of UK milk legislation with a view to simplifying and consolidating it for the benefit of the dairy trade. By and large Directive 92/46

reflects much of what is already in UK milk hygiene legislation (particularly in regard to cows milk) and it is intended that the implementing regulations, once introduced, will be the single piece of legislation, together with any future amendments to it that may be necessary, covering hygiene rules for the production and marketing of dairy products. In addition there will be a Code of Practice which will give guidance to enforcement officers (and industry) on the requirements of the regulations.

REVIEW OF EXISTING LEGISLATION

6. Our review of UK milk legislation has concluded that for public health reasons we should retain certain provisions from current legislation relating to heat-treatment and production of cream and dairy ice-cream. These will be included in the Dairy Products (Hygiene) Regulations. In addition, certain provisions in the Milk and Dairies (General) Regulations 1959, as amended, relating to communicable diseases will be retained on a short term basis until they can be included in horizontal public health legislation. Apart from these Regulations and the Ice-Cream (Heat Treatment) Regulations 1959, which will be amended to cover non dairy ice cream, all other dairy hygiene legislation will be revoked. In Scotland [and in Northern Ireland] the corresponding legislation will be reviewed in a similar way.

BASIC PHILOSOPHY

7. The Directive applies to all premises which produce and place on the market raw milk, heat-treated drinking milk, milk for the manufacture of milk-based products and milk-based products intended for human consumption. It does not, however, apply to most retail premises, including catering establishments, cafes and mobile vehicles, which sell milk and milk-based products eg to the ultimate consumer. Member States also have some discretion to apply national rules to raw milk and raw milk-based products sold directly by the producer to the consumer (see Section 4, paragraph 2). All sales of raw cows milk for drinking will however continue to be banned in Scotland.

8. The EC Commission has advised that milk-based products should be defined as:

- (a) milk products - whey, cream, cheese, butter, butteroil, buttermilk, anhydrous milk fat, yogurt, kephir, partly and wholly dehydrated milk products, caseins and caseinates and lactose and
- (b) composite milk products - which are products where
- (i) no part replaces or is intended to replace any milk constituent

AND

- (ii) milk or milk product is an essential part either in terms of quantity OR for characterisation of the product. The Commission has prepared a document which helps to clarify the type of composite milk products within the scope of the Directive (Document VI/8972/93-EN). According to this document, the crucial factor is the definition of "essential part", so that products containing small amounts of milk or milk products are excluded (e.g. milk chocolate, biscuits containing butter, whisky cream). The document does not specify a percentage of milk/milk products, but a guideline figure of 50% is inferred. A composite milk product may contain less than this amount of milk/milk product, if the milk ingredient is essential in terms of characterisation. Examples of composite milk products are dairy ice cream and dairy desserts such as crème caramel and custard.

9. All premises with one or more cows, goats, sheep, and buffaloes will need to be registered with ADAS in England/Wales (or licensed in Scotland and in Northern Ireland with the appropriate authority), if they are producing milk for sale. A separate leaflet - issued to all cows milk producers - covers the requirements for production holdings.

10. All premises heat-treating milk or processing dairy products for sale (including those engaged in slicing, and/or packaging, bottling, wrapping or re-wrapping such products) will need to be approved by the food or enforcement authority who will have overall responsibility for supervising the necessary high standards of hygiene in such premises. An approval number for the premises will be issued, and will have to be shown on the commercial document (see Section 6, paragraph 15). From 1

January 1995 (we expect this to be extended to 1 January 1996) it must also appear as part of the health mark on milk and milk based products produced and traded in both the UK and throughout the EC (see Section 6, paragraphs 3-11).

11. As this booklet makes clear, certain aspects associated with the Directive still have to be decided. In particular the Commission has proposed a number of amendments to the Directive which will benefit industry, but which have still to be agreed in Brussels. Any amendments agreed which have a bearing on these requirements will be notified as appropriate to industry and enforcement authorities and individual processors may wish to keep in touch with their local enforcement officer.

SECTION 2

REGISTRATION, LICENSING AND APPROVAL OF DAIRY PREMISES

PRODUCTION HOLDINGS (DAIRY FARMS)

1. The Directive makes it clear that only raw milk coming from particular animals and holdings meeting certain standards can be used for raw drinking milk and for the manufacture of milk-based products or heat-treated drinking milk. Those standards are referred to in Section 3. The regulations implementing the Directive in the UK will require that production holdings meeting the hygiene standards should:

- in England and Wales be registered (as cows' milk producers currently are under the Milk and Dairies (General) Regulations 1959);
- in Scotland be licensed (as they are under the Milk and Dairies (Scotland) Regulations 1990);
- in Northern Ireland be licensed (as they are under the Milk Regulations (Northern Ireland) 1987).

Cows milk production holdings already registered or licensed under the above-mentioned existing legislation will automatically be registered or licensed under the forthcoming legislation. Goats, sheep and buffalo milk producers will, however, need to apply for registration or a licence, as appropriate, to the relevant enforcement authority as this will be the first time they will be subject to specific milk hygiene legislation. A leaflet giving guidance on the requirements relating to dairy farms is available separately as is a separate explanatory leaflet for goat and sheep milk producers and processors(see page 34 for details).

PROCESSORS

2. Each Member State is required to approve processing and treatment establishments and collection and standardisation centres which meet the terms of the Directive (see Section 4). Food or enforcement authorities are responsible for issuing approval numbers to establishments. Those establishments which are granted a temporary derogation (see Section 8) from certain equipment and structural requirements can sell their products on the national market only.

SECTION 3

CONDITIONS TO BE MET ON PRODUCTION HOLDINGS (DAIRY FARMS)

ANIMAL HEALTH REQUIREMENTS

1. Raw cows and raw buffaloes milk can only originate from production holdings with herds which are officially tuberculosis-free, and brucellosis-free or officially brucellosis-free. Milk from goats and sheep can only originate from holdings which are brucellosis-free or officially brucellosis-free (*Brucella melitensis*). However, milk from healthy animals in herds/flocks which are not officially tuberculosis-free or brucellosis-free or officially brucellosis-free can be used for the manufacture of heat-treated milk or for the manufacture of milk-based products following heat treatment under the supervision of the competent authority. In the case of goats and sheep milk this heat-treatment must take place on the production holding.

2. In addition, the animals should not show any symptoms of infectious diseases communicable to humans through milk nor should they give the milk any abnormal organoleptic characteristics. The animals should not have any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognisable inflammation of the udder (or udder wound likely to affect the milk).

HYGIENE REQUIREMENTS

The Holding

3. All holdings (except those used solely for producing milk for consumption by the owner/occupier) must be registered (or licensed) (see Section 2, paragraph 1 of this booklet) and animals on holdings will undergo regular veterinary inspections.

4. If animals are housed, the premises must ensure good conditions:

- of housing, hygiene, cleanliness and health of the animals;
- of hygiene for milking, handling, cooling and storing the milk.

5. Where milking is carried out or milk is stored, handled or cooled the premises must:

- be easy to clean and disinfect with easy-to-clean walls and flooring;
- have flooring which allows draining of liquids and easy disposal of waste;
- have adequate ventilation and lighting;
- have a sufficient supply of potable water meeting current drinking water quality standards¹;
- be separate from contamination sources;
- have fittings and equipment which are easy to clean and disinfect.

6. If milk is stored at the holding, those premises must have suitable milk refrigeration equipment, adequate vermin control and be separated from animal housing.

7. If a moveable milk bail is used, there must be a sufficient supply of potable water and the fittings and equipment should be easy to clean and disinfect. In addition, the bails should be sited on fresh ground free from waste matter and milk should be protected. The construction of the bails should allow interior surfaces to be kept clean.

8. If the milk-producing animals are kept untethered in the open, the milking parlour/area must be separated from any housing area.

9. The isolation of infected animals (see paragraphs 1 and 2 of this Section) should be effective.

Milking

10. Milking must be carried out hygienically and the milk must be placed in a clean place to avoid adverse effects on it. For temperature requirements see Section 5, paragraph 23, of this booklet.

¹ Directive 80/778/EEC

Premises and Equipment

11. Utensils, containers, tanks etc. intended for milking, collection or transport must be of smooth material which resists corrosion, is easy to clean and disinfect and does not transfer to the milk substances which will endanger human health or affect the compositional or organoleptic characteristics of the milk.
12. After use, such utensils or equipment which come into contact with the milk must be cleaned and disinfected. Containers and tanks used to transport milk must be cleaned and disinfected after each use.

Personnel

13. Personnel must observe high standards of cleanliness and those milking and handling raw milk must wear suitable clean milking clothes. Hands must be washed before milking and should be kept as clean as possible during milking. Persons who may be liable to contaminate raw milk must not milk animals or handle raw milk.

COMPOSITION OF MILK

14. In order to prevent water being added to raw milk, a monitoring system will be established under the supervision of the competent authority. This system will include checks on the freezing point of milk from each production holding through random sampling of raw milk.
15. Directive 92/46 states that heat-treated drinking milk from cows must have a freezing point not higher than -0.520°C . However, the EC has recently agreed an amendment (Commission Decision 94/330/EC) which would mean that this figure need not be met providing no water has been added to the milk. In addition, such milk must have a density of not less than 1028 grams per litre and contain a minimum of 28 grams of protein per litre, although the Commission is also reviewing these figures.

SECTION 4

CONDITIONS TO BE MET BY DAIRY PROCESSORS (APPROVED ESTABLISHMENTS)

1. Premises processing milk and milk products (collection and standardisation centres, treatment or processing establishments) can only use milk from registered/licensed production holdings or from other approved establishments. As stated in Section 2, all establishments meeting the terms of Directive 92/46 will be approved. Those establishments covered by Directive 92/47 (see Section 8) which have been granted temporary derogations will also be approved but will not be able to use the EC health mark. Stand-alone storage depots/warehouses do not need to be approved.

2. In the case of processing premises of producer/processors selling direct to consumers their total production of raw milk or raw milk-based products processed on the premises from their own milk, there is discretion in the Directive to apply national rules to such sales. We are now proposing to exempt such premises from the need for approval although they will have to meet general hygiene conditions applicable to processing establishments set out in paragraphs 6-9 of this Section and HACCP checks and training requirements (see Section 7 paras 1 and 3). However, premises from which these products are sold can be given an approval number and their products can carry the health mark if they meet the requisite standards for approval under Directive 92/46. If establishments are in any doubt as to whether approval is necessary, advice should be sought from the local enforcing authority.

TREATMENT AND PROCESSING ESTABLISHMENTS

Working areas

3. These establishments must have working areas large enough for work to be carried out under hygienic conditions and, if the production of some products might pose a risk of contamination to other products covered by Directive 92/46, the production must be carried out in a physically separate working area or in the same working area but at different times.

4. In working areas there should be:

- solid waterproof flooring which is easy to clean and disinfect and which has good drainage;
- easy to clean walls, ceilings or roof linings;
- easy to clean non-corrodible doors;
- adequate natural or artificial lighting and ventilation with, if appropriate, good steam and water vapour extraction facilities.

5. There should be hot and cold running water in order to clean and disinfect hands. In milk rooms and toilets the taps used for hand washing must be designed to be non-hand-operable (elbow-operated and automatic cut off taps are permitted). Provision in these facilities for storage of cleaning and disinfecting materials and hygienic means of drying hands must be made. There should also be facilities for cleaning tools, equipment and installations.

Storage areas

6. All storage areas must meet the same hygiene standards as working areas. However the Commission has proposed that separate facilities for hand washing and cleaning equipment will not be necessary. In chilling and refrigeration rooms, a floor which is easy to clean and disinfect and which is well-drained is sufficient, and providing they were built before 1.1.93, wooden walls in chilling and refrigeration rooms are acceptable. In freezing and deep-freezing rooms, easy to clean, waterproof and rot-proof flooring is sufficient.

General

7. There should be facilities for the hygienic handling and protection of raw materials and exposed final products during loading and unloading. There should be protection against pests. All equipment in direct contact with raw materials should be of corrosion-resistant material and be easy to clean and disinfect. Raw materials or products not intended for human consumption should be placed in special water-tight non-corrodible containers.

8. There should be a waste-water disposal system and a supply of potable water meeting current drinking water quality standards. Non-potable water can, however, be used for steam production, fire fighting and refrigeration equipment as long as the pipes are clearly distinguishable from those carrying the supply of potable water.

9. There must be adequate changing facilities with smooth, waterproof, washable walls and floors and with washbasins and flush lavatories (which should not open directly on the milk rooms). Taps fitted to hand wash basins must be designed to be non-hand-operable (elbow-operated taps or automatic cut off taps are permitted). Processing establishments on farms need not provide changing rooms if the establishment is adjacent to the farmhouse or if the scale of the business does not warrant separate changing rooms eg. a changing area will suffice.

10. There must be a room, cupboard, or a secure place for the storage of detergents, disinfectants, cleaning and maintenance material. Where appropriate, there should be facilities for cleaning and disinfecting tanks used for transporting milk and liquid or powdered milk-based products.

Equipment

11. Treatment and processing establishments which package heat-treated drinking milk and liquid milk-based products eg. cream/drinking yogurt, must have equipment for the mechanical filling and automatic sealing of containers (excluding churns and tanks). Permanent derogations from this requirement are available and temporary derogations were available to larger establishments in Spring 1993 (see Section 8). The requirement for mechanical filling and automatic sealing is new to industry in the UK and therefore has been identified as a condition which the industry may have problems in meeting. In our proposed implementation of the Directive, tanks will be taken to include pergalis and large containers used in the catering trade which are not automatically sealed. The Commission has now proposed that all bulk packaging of over 4 litres should be exempt from the mechanical filling/automatic sealing requirements and that competent authorities may authorise alternative sealing requirements in the case of limited production providing assurances of hygiene are given. In the case of limited production (establishments and lines) we will be interpreting "limited production" as usage of no more than 300,000 litres of milk (equivalent) per year. The mechanical filling and automatic sealing requirement does not cover frozen milk-based products such as dairy ice-cream.

12. Establishments must have equipment for the cooling and cold storage of raw milk, heat-treated milk and milk-based products. Cold stores must have correctly calibrated temperature-recording apparatus.

13. When using disposable containers, establishments must have an area for their storage and for materials used in their manufacture. When using reusable containers, there should be a special storage area for them and for the equipment used to clean and disinfect them mechanically.

14. Where appropriate, establishments must have containers for storing raw and standardised milk and standardisation equipment and centrifuges or other suitable means for physically purifying milk. In addition, where appropriate, establishments must have equipment for the cooling, wrapping and storage of frozen milk-based products and for the drying and wrapping of powdered milk-based products.

15. Where installed heat-treatment equipment must have:

- (a) an automatic temperature control,
- (b) a recording thermometer,
- (c) an automatic safety device preventing insufficient heating,
- (d) an adequate safety system preventing the mixture of heat-treated milk with incompletely heated milk, and
- (e) an automatic recording device for the safety system referred to in (d) above.

These heat-treatment requirements go beyond the fittings normally associated with batch pasteurisers (used in some dairies and by some ice-cream manufacturers). However, the Commission has proposed that the competent authority may accept different equipment which provides equivalent performance with the same health guarantees. Batch pasteurisers can therefore continue to be used as at present provided that full agreement is given from the enforcing authority.

Hygiene conditions:

(a) Premises and equipment

16. All equipment and instruments must be kept clean and in good condition in order to stop contamination of raw materials or products. Animals are prohibited in working and storage areas and substances used for controlling vermin must be stored in lockable cupboards or rooms. Disinfectants and similar substances need to be acceptable to the food authority on the basis that they are suitable for the purpose and

used in such a way that they do not have adverse effects on machinery, equipment and products.

17. In order to achieve high standards of food safety an appropriate risk analysis programme should be drawn up, following the principles of Hazard Analysis Critical Control Points (HACCP). Where possible cross contamination should be avoided. Rooms used for production should have separate wet and dry areas, each with their own operating conditions. It may be appropriate that these activities be separated in time to avoid risks of contamination. After each journey, or each series of journeys where there is only a very short period of time between unloading and the following loading, containers and tankers used to transport milk to an establishment must be cleaned and disinfected before re-use. The cleaning programmes for equipment, containers and installations which come into contact with perishable milk or milk-based products during production and for equipment, containers and installations which come into contact with microbiologically stable milk-based products and rooms in which they are stored must be based on the principles of HACCP. The treatment premises must also be cleaned in accordance with procedures based on HACCP principles.

(b) Personnel

18. A high standard of cleanliness is required of all personnel. Suitable clean working clothes and clean head gear which completely encloses the hair must be worn. Personnel working with raw materials and products covered by the Directive must wash their hands at least each time work is resumed and/or when contamination has occurred. Any wounds to the skin must be covered with a waterproof dressing. There should be no smoking, spitting, eating or drinking in work or storage areas. All food handlers being recruited to work in establishments will need to demonstrate, through a medical certificate, that there is no medical impediment to such employment. Separate guidance will be available shortly on medical certification [from the Department of Health and SOAFD].

COLLECTION AND STANDARDISATION CENTRES

19. It is not thought that any such centres exist at present in the UK. However such establishments must meet the requirements specified in paragraphs 3-10.

20. In addition, collection centres must have cooling equipment or appropriate means for cooling milk and, if milk is stored at the collection centre, a cold-storage installation. If milk is purified at the collection centre there must be centrifuges or any other apparatus suitable for the physical purification of milk. Standardisation centres must have containers for the cold storage of raw milk, standardisation equipment and containers for the storage of standardised milk, and centrifuges or any other apparatus suitable for the physical purification of milk.

SECTION 5

STANDARDS (HYGIENE AND MANUFACTURING) FOR RAW MILK, HEAT-TREATED MILK AND MILK-BASED PRODUCTS

1. Hygiene standards are laid down relating to raw milk (when collected from the production holding or for acceptance at the treatment or processing establishment). There are also hygiene requirements for the manufacture of heat-treated milk and milk-based products, and microbiological criteria for milk-based products and drinking milk.

RAW MILK

2. Raw cows milk to be used for the production of heat-treated drinking milk, fermented milk, junket, flavoured milk or cream must have a:

Plate count at 30°C (per ml)	≤ 100,000
Somatic cell count (per ml)	≤ 400,000

3. Raw cows milk for the production of other milk-based products must have a:

Plate count at 30°C (per ml) -	from 1.1.94 ≤ 400,000
-	from 1.1.98 ≤ 100,000

Somatic cell count (per ml) -	from 1.1.94 ≤ 500,000
-	from 1.1.98 ≤ 400,000

4. Where raw cows milk is to be used for the manufacture of raw milk-based products whose manufacture does not involve any heat-treatment ie at least equal to pasteurisation, such milk must meet the standard in paragraph 2 and the following standard for *Staphylococcus aureus*: n=5 c=2 m=500 M=2000 (see paragraph 19 for an explanation of n, c, m and M).

5. Raw goats and sheep milk to be used for the production of heat-treated drinking milk or heat-treated milk-based products must have a plate count at 30°C (per ml) of less than or equal to 1,000,000 (the Commission has proposed an increase in this figure). Standards relating to the plate count and somatic cell count applicable from 1.1.98 will be decided later.

6. Where raw goats or sheep milk is to be used for manufacturing a milk-based product without any heat-treatment, such milk must have a plate count at 30°C (per ml) of less than or equal to 500,000 and meet the *S. aureus* standard for raw cows' milk (ie. $n=5$ $c=2$ $m=500$ $M=2000$).
7. Raw buffaloes milk is subject to the same standards as raw sheep and goats milk except that somatic cell count standards apply ($\leq 500,000$ in the case of milk going for heat treated products and $\leq 400,000$ in the case of raw milk for raw milk products).
8. All plate count figures should be based on a geometric average over a period of two months, with at least two samples a month, and somatic cell count figures should be based on a geometric average over three months, with at least one sample a month. Standards can be measured at the production holding or on arrival at the treatment or processing establishment or with the first buyer. Limits for antibiotic residues in milk laid down in Annex I and III to EC Regulation 2377/90¹ as amended will also apply. It will be the responsibility of operator/managers (or first buyers eg Milk Marque where raw milk is purchased direct from a production holding) to ensure that raw milk is checked against standards in the Regulations. However the Commission has proposed that standards should be measured only in relation to milk from one production holding. This causes problems for the UK in respect of somatic cell counts and we are opposing this proposal in Brussels.

REQUIREMENTS FOR THE PRODUCTION OF HEAT-TREATED DRINKING MILK

9. Raw cows milk to be used for the manufacture of heat-treated drinking milk must meet the standards of paragraph 2 above. If treatment of the raw milk has not begun within 36 hours of the milk's acceptance at the dairy, the plate count at 30°C must not exceed 300,000 per ml if the milk is to be heat-treated. If milk has had a previous pasteurisation it must have, before the second heat treatment, a plate count at 30°C of less than 100,000 per ml.
10. Pasteurised milk must be obtained by means of a heat-treatment involving a high temperature for a short time (at least 71.7°C for 15 seconds or any equivalent combination) or a pasteurisation process using different time and temperature

¹ Council Regulation (EEC) No. 2377/90 of 26 June 1990 laying down a community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.

combinations to obtain an equivalent effect, and must show a negative reaction to the phosphatase test and a positive reaction to the peroxidase test or, in the case of high-temperature pasteurised milk, show a negative reaction to both tests.

[The Commission has made proposals that would prevent milk pasteurised in one establishment being sent for second pasteurisation in another establishment (double pasteurisation) and still being called pasteurised milk. This is a practice common in the UK for production of a proportion of our low fat milk. We are discussing this matter with the Commission].

11. UHT milk must be obtained by applying heat to a continuous flow of raw milk entailing the application of a high temperature for a short time (not less than +135°C for not less than one second).

12. Sterilised milk must have been heated and sterilised in hermetically sealed wrappings or containers, the seal of which must remain intact. Alternatively, the continuous flow process may be used.

REQUIREMENTS FOR MILK FOR THE MANUFACTURE OF MILK-BASED PRODUCTS

13. For the manufacture of all milk-based products use of the raw milk must start within:

- 36 hours of acceptance at the dairy if the milk is kept at a temperature not exceeding 6°C; and
- 48 hours of acceptance at the dairy if the milk is kept at a temperature not exceeding 4°C.

However, the Commission has proposed that a further category be added - that the raw milk has to start being used as soon as possible after acceptance at the dairy if the milk has not been refrigerated. The Commission has also proposed that the approving authority may, for technological reasons, authorise these time and temperature limits to be exceeded.

14. Heat-treated milk to be used in the manufacture of milk-based products must have come from raw milk meeting the standards laid down in paragraphs 2, 3, 5, 6 and 7 (as appropriate) of this section.

15. If thermised milk is to be used for the manufacture of milk-based products the thermised milk must:

- (a) be obtained from raw milk which must, if not thermised within 36 hours, have a plate count at 30°C less than 300,000 per ml before thermisation;
- (b) have come from raw milk treated for at least 15 seconds at a temperature between 57°C and 68°C; and
- (c) if thermised milk is to be used for the production of pasteurised, UHT or sterilised milk intended for the manufacture of milk-based products, it must have, before treatment, a plate count at 30°C of not more than 100,000 per ml.

16. If pasteurised or UHT milks are to be used, the milk must meet the requirements as laid down in paragraphs 10 and 11 as appropriate.

MICROBIOLOGICAL CRITERIA FOR MILK-BASED PRODUCTS

17. Schedule 6 of the Dairy Products (Hygiene) Regulations will lay down microbiological standards for milk-based products. These standards will be applicable on removal from the processing establishment. They will not apply to retail sales.

18. The standards will be grouped into two tables - compulsory criteria (for pathogens) and analytical criteria (for organisms indicating poor hygiene). The action required if standards are exceeded will vary - for example if the standards for pathogens are exceeded, the product will have to be withdrawn from the market. The Directive also includes guidelines for indicator organisms which operators will find it helpful to follow.

19. The sampling plans laid down in these tables will be used for enforcement purposes. Manufacturers will, however, have to carry out their own sampling (in accordance with a risk analysis programme) in order to demonstrate that their production meets the standards laid down in Schedule 6.

20. The sampling plans laid down in Schedule 6 will use the ICMSF (International Commission of Microbiological Specifications for Foods) format ie. "n" "c" "m" "M".

These will be fully defined in the Regulations. Briefly, the level of test organism which will be acceptable and attainable in the product will be denoted by 'm', and 'M' will be the hazardous or unacceptable level of contamination. 'n' will define the number of sample units required for testing. Microbial counts between 'm' and 'M' are undesirable but some will be accepted, the number acceptable is denoted by 'c'.

MICROBIOLOGICAL CRITERIA FOR DRINKING MILK

21. Schedule 4 of the Dairy Products (Hygiene) Regulations will lay down the microbiological criteria for drinking milk, both raw and heat-treated. In the case of raw cows milk for drinking (paragraph 2 of Part I of Schedule 4) the standards will apply only where milk is being exported. In addition there are other microbiological standards for heat-treated milks and these will have to be assessed in accordance with the principles described in paragraphs 19 and 20 of this Section. Raw milk for drinking for direct sale to consumers in the UK is subject to different requirements (see paragraph 23 below).

22. In addition to the microbiological standards described above, heat-treated drinking milk must not contain pharmacologically active substances in quantities higher than the limits laid down in Annexes I and III to Regulation 2377/90 (as amended).

DIRECT SALES OF RAW DRINKING MILK

23. As indicated in Section 1, the Directive allows Member States to maintain their national rules relating to direct sales of raw drinking milk to consumers. In Scotland the current ban on sales of raw cows milk for drinking will continue. Raw goats and sheep milk for drinking will be able to be sold but only through certain outlets. In England and Wales (and in Northern Ireland) raw cows drinking milk can only be sold at the farm gate by a licensed producer or farmhouse caterer (or via a licensed distributor). It has to meet certain microbiological standards (for plate count and coliforms) and also has to carry a health warning. These arrangements will be continued (except that in England and Wales the requirement for licensing for producers and distributors will be dispensed with) and microbiological standards will be extended to raw goats and sheep milk. All raw milk will be required to carry a health warning. (This requirement is contained in draft consolidated Food Labelling Regulations which were the subject of a recent consultation with interested parties).

Raw drinking milk intended for export to another Member State must meet the microbiological standards in Schedule 4, Part I, paragraph 2 of the Dairy Products (Hygiene) Regulations.

TEMPERATURES

24. Reference has already been made in paragraph 13 to the temperature requirements for raw milk before treatment. In addition, on production holdings where cows' milk is not collected within 2 hours of milking, it must be cooled to a temperature of not more than 8°C if there is a daily collection, or not more than 6°C if collection is not daily. During transport to the treatment establishment the temperature must not exceed 10°C. The Commission has proposed some relaxation in these temperatures.

25. After acceptance at a treatment establishment, and if not treated within four hours, milk must be cooled to a temperature not exceeding 6°C and maintained at that temperature until heat-treated. As already described in paragraph 13, if the raw milk is not to be treated or used for 48 hours it must be cooled to 4°C or lower.

26. Other storage and transport requirements will be set out in Schedules 7 and 8 of the Dairy Products (Hygiene) Regulations.

SECTION 6

RULES ON WRAPPING, PACKAGING, HEALTH MARKING, LABELLING, STORAGE, TRANSPORT AND DOCUMENTATION

WRAPPING AND PACKAGING

1. Wrapping and packaging material must comply with all the rules of hygiene and be strong enough to protect products effectively from physical damage and from contamination. Wrapping and packaging operations must take place under hygienic conditions and in rooms (or designated areas) provided for that purpose. However, product manufacturing and wrapping/packaging operations can take place in the same room provided that:

- the room is sufficiently large to ensure that the hygiene of the operations is assured;
- the wrapping and packaging material has been placed in protective covers immediately after its manufacture and is brought to the processing establishment while in such covers and stored there hygienically in a special room;
- the storage room referred to above is vermin and dust-free and is separated from rooms containing substances which could contaminate the products;
- the packaging is assembled hygienically before being brought in to the room (if not assembled automatically);
- the packaging is used without delay (and is not handled by staff handling unwrapped products if there is a risk of contamination); and
- immediately after packaging the products are placed in storage rooms/areas.

2. The sealing of containers of heat-treated milk and liquid milk-based products must take place in the treatment establishment where the last heat-treatment was carried out, immediately after filling, and with a sealing device which, once broken, can be easily seen and checked. Sealing must be carried out automatically except in

the case of limited production (lines) where the Commission has proposed that non-automatic sealing is acceptable (see Section 8).

HEALTH MARKING AND LABELLING

3. Subject to the exemptions described in paragraph 7 of Section 1 and paragraph 2 of Section 8, all products covered by the Directive and originating from approved establishments must carry a health mark. Such marking, carried out during or immediately after manufacture, should be visible, legible, indelible and easily distinguishable.

4. The health mark can be applied anywhere on the product or the wrapping (if the product is individually wrapped) or to a label on the wrapping. However if a product is individually wrapped and subsequently packaged, eg. a box of individually wrapped cheese portions, the health mark need only be applied to the packaging. The Commission has proposed that this exemption should be extended to all small packages to be supplied to the ultimate consumer.

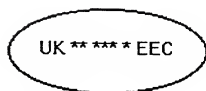
5. If products wrapped and/or packaged in accordance with paragraph 4 are further packaged eg. in a cardboard box, the health mark must be applied to the further packaging.

6. The health mark must appear in the following form:

Insert approval number where asterisked

- ** Local Authority prefix eg. AB. (In Northern Ireland the prefix will be NI).
- *** Approval number eg. 001
- * M - Optional if agreed with the approving authority

EITHER



OR



(The United Kingdom can be abbreviated to UK for the UK market - it has yet to be clarified whether this abbreviation will be acceptable for trade with other Member States).

7. The health mark can be applied by an ink stamp or by branding or may be printed on or applied to a label. The health mark can also be an irremovable plate of resistant material with the information described in paragraph 6.

8. For heat-treated milk and liquid milk-based products the labelling on the packaging must also show (for the purpose of checks by enforcement authorities):

- (a) the type of heat-treatment which the raw milk had undergone and
- (b) information allowing the date of last heat-treatment to be established together with, for pasteurised milk, the temperature at which the product should be stored (ie. 6°C).

Reusable glass bottles are expected to be exempt from these requirements.

9. Again for enforcement purposes, raw milk intended for direct human consumption must be labelled "raw milk". Similarly, milk-based products made from raw milk without heat treatment should be labelled "made with raw milk". These requirements do not apply at the retail stage.

10. Health marking will be a problem for some traditional UK products, in particular milk in glass bottles, where the only area available for accurate labelling is the foil cap. However, the Commission has proposed that reusable glass bottles and receptacles with a largest surface area of less than 10cm² (expected to be increased to 25 cm² shortly) may carry an abbreviated form of health mark containing only the initials of the consigning country and the number of the establishment. The Commission has also said that small individual packaged units eg impulse ice cream need not be health marked and the Directive is expected to be amended to reflect this.

11. The Commission has also proposed a delay in the introduction of health marking requirements (until 1 January 1995 expected to be extended to 1 January 1996) during which time milk and milk-based products (which are not health marked) can be traded with other Member States provided the health mark/approval number is shown on the accompanying commercial document. It is also expected to propose some further flexibility in health marking requirements so as to allow the approval number to be printed outside the oval EC health mark.

STORAGE AND TRANSPORT

12. The milk and milk-based products covered by the Directive which cannot be stored at ambient temperatures must be stored at temperatures established by the manufacturer to ensure their durability. Pasteurised milk, when kept in the establishment and when transported in tanks or packed in small containers and churns, must not exceed 6°C. The 6°C temperature requirement does not apply either to milk delivered to consumers' doorsteps or to small retail outlets by vehicles either solely engaged in making deliveries to consumers' doorsteps or also engaged in making deliveries to small retail outlets and institutions or schools. In addition, the Commission has proposed a tolerance of +2°C for other deliveries of pasteurised milk to retail establishments.

13. Tanks, churns and other containers used to transport pasteurised milk must:

- have inside surfaces made of smooth material which is easy to clean and disinfect, which resist corrosion and which do not transfer substances to the milk so as to endanger human health or impair the composition or organoleptic characteristics of the milk; ..
- be designed to allow milk to drain away completely and taps, if fitted, should be easy to remove, clean and disinfect;
- be cleaned and disinfected immediately after each use and at least once every 24 hours; and
- be sealed before and during transport with a water-tight sealing device.

14. Milk tankers must only be used for the transportation of foodstuffs. Other vehicles used for transporting heat-treated milk must not be used to transport any other product or object which could lead to the milk deteriorating. The internal surfaces of such vehicles must be smooth and easy to wash and disinfect.

DOCUMENTATION

15. During transport heat-treated drinking milk and milk-based products must be accompanied by a commercial document which must show the details of the EC health mark of the establishment consigning the product and:

- for heat-treated drinking milk or milk-based products, allow the nature of the heat-treatment and the supervising competent authority to be identified; and
- be kept by the consignee for at least one year.

16. However, such an accompanying document is not required when milk and milk-based products are delivered direct by the producer/manufacturer to the final consumer. In effect this will mean that any doorstep deliveries to local shops will be exempt from this requirement. In any event it will be acceptable for the information specified in paragraph 15 to be placed on sales or advice/invoice notes. Where consignments are split, copies of the commercial document will suffice.

17. As indicated in paragraph 11, the EC health mark/approval number on the commercial document will be the sole means of telling whether products can be traded - where products are not themselves health marked - during the transitional period.

SECTION 7

HEALTH CHECKS/INSPECTIONS/TRAINING

OPERATOR/MANAGER OF ESTABLISHMENT

1. The operator or manager of an establishment must ensure that checks are carried out which allow him to:

- identify points critical to the safety of food, based on a risk analysis programme (MAFF/DH and DANI information leaflets entitled "*Hazard Analysis Critical Control Point (HACCP): Practical food safety for businesses*" are available from food authorities) in establishments on the basis of the processes used;
- monitor and check these critical points appropriately;
- take samples for analysis in a recognised laboratory to check cleaning and disinfection methods and compliance with the standards in the Directive;
- keep a record of the above for at least two years (two months for milk-based products which cannot be stored at ambient temperatures);
- inform the competent authority if the laboratory examination reveals a serious health risk; and
- withdraw any products considered to be a risk which will then be under the supervision and control of the competent authority.

2. The correct administration of the health mark described in paragraph 6 of Section 6 must be guaranteed by the operator or manager.

TRAINING

3. All personnel should receive appropriate training commensurate with the work activity and the type of work being undertaken in the dairy establishment.

COMPETENT AUTHORITY

4. All establishments should be supervised by the competent authority to ensure that the establishments are meeting the requirements of the Directive. This will include the taking of samples required for laboratory tests.
5. In order to carry out these checks on compliance with the Directive the competent authority must have free access at all times to the cold stores and all the working premises.
6. The competent authority in England, Wales and Scotland will be the Local Authority (LA) (Environmental Health Department or in some cases Trading Standards Department). In Northern Ireland this will either be the LA or the Department of Agriculture for Northern Ireland.

SECTION 8

DEROGATIONS

COUNCIL DIRECTIVE 92/47/EEC (TEMPORARY DEROGATIONS)

1. When Directive 92/46 was agreed it was accepted that some dairy establishments might not immediately be able to meet some of the structural and equipment standards contained in that Directive.
2. Directive 92/47 therefore allows Member States to authorise establishments to temporarily derogate from some of the structural and equipment requirements of Directive 92/46 (Section 4, paragraphs 1-13 of this booklet). These authorisations will be temporary and on the condition that any aspects of Directive 92/46 which cannot be met now must be complied with by the end of 1997. Such establishments will, however, still be approved by the food authority. Products from those establishments which are authorised to temporarily derogate from some of the structural and equipment requirements will not be able to carry the EC health mark (see Section 6, paragraph 6) and can only be traded on the national market.
3. Operators of establishments will be aware of the temporary derogation exercise carried out in 1993 by ADAS and EHOs in England and Wales, DANI staff in Northern Ireland and by the Food & Dairy Unit of SOAFD in Scotland. The UK submitted to the EC Commission a list of establishments to be considered for temporary derogations and these have now been included in an agreed EC list.
4. In the United Kingdom our national legislation on milk hygiene means that establishments are already able to comply with most of the structural and equipment requirements of Directive 92/46. The majority of applications that the UK put forward therefore related to the requirement for establishments to have equipment for mechanically filling and automatically sealing containers of heat-treated milk and liquid milk-based products (as many UK establishments do not possess such equipment). The UK also submitted a few applications relating to establishments which are undergoing major refurbishment and could demonstrate through work plans and a completion date that they would soon comply with the requirements of Directive 92/46.

5. Directive 92/47 also enables Member States to grant temporary derogations to establishments which cannot obtain supplies of raw milk meeting plate count and somatic cell count standards in Annex A Chapter IV of Directives 92/46. The UK will be taking advantage of this provision in the Dairy Products (Hygiene) Regulations.

ARTICLE 11 OF COUNCIL DIRECTIVE 92/46 (PERMANENT DEROGATIONS)

6. Article 11 of Directive 92/46 allows Member States to approve establishments manufacturing a limited amount of milk-based products, even if they cannot satisfy some of the structural, equipment and hygiene aspects of the Directive (Section 4 of this booklet). It is for Member States to determine what is a low capacity establishment and from which particular requirements it should be possible to derogate permanently (although it is possible that the EC Commission may propose harmonised criteria in the future).

7. In the United Kingdom low capacity establishments have been defined as those using no more than 300,000 litres of liquid milk (or its equivalent ie including that quantity of milk required to produce any milk products used) each year to make milk-based products. Because most of the Directive's requirements on structure, hygiene and equipment are already included in UK legislation, it is expected that there will be few cases where food authorities will find it necessary to give permanent derogations, although goats and sheep milk product processors may have more difficulty in meeting requirements and so may need derogations.

8. Permanent derogations are not available at present for those processors who solely produce liquid milk. However, the Commission recognises that this is anomalous and is proposing an amendment to the Directive so as to exempt all processors with limited production (including limited production lines) from the need for automatic sealing of containers.

9. All products from establishments receiving permanent derogations will be entitled to use the EC health mark.

CHEESE DEROGATION

10. Establishments making cheeses which, in their manufacture, require to be aged or ripened for at least 60 days may be granted permanent derogations from:

- the standards for raw milk (Section 5, paragraphs 2-7 of this booklet);
- the structural, equipment and hygiene standards (Section 4 of this booklet) and wrapping and packaging requirements (Section 6, paragraphs 1 and 2 of this booklet) (as long as the final product can meet the appropriate standards of Section 5, paragraphs 17-19 of this booklet);

11. UK authorities think that there will be very few cheese manufacturers who will qualify for this derogation. However, there is no time limit for the receipt of applications under this provision and the United Kingdom authorities are prepared to consider any reasonable request to make use of this derogation. Any processor wishing to make a request should contact MAFF, Milk and Milk Products Division.

SECTION 9

FURTHER INFORMATION

England and Wales

For further information about the requirements of the Regulations in England and Wales, please contact your Local Authority's Environmental Health Department. Additional information is available by contacting:

The Ministry of Agriculture, Fisheries and Food
Milk and Milk Products Division
Room 519
Whitehall Place (East)
London SW1A 2HH
Telephone: 071 270 8243

The Welsh Office Agriculture Department
Cathays Park
Cardiff
CF1 3NQ
Telephone: 0222 823624

The Department of Health
Health Aspects of Environment & Food Division
Skipton House
80 London Road
London SE1 6LW
Telephone: 071 972 5345

Scotland

For further information please contact:

The Scottish Office Agriculture and Fisheries Department
Meat, Fish and Milk Hygiene Branch
Pentland House
47 Robb's Loan
Edinburgh EH14 1TY
Telephone: 031 244 6413

Northern Ireland

For further information please contact:

The Department of Agriculture for Northern Ireland
Milk and Milk Products Quality Assurance Division
Dundonald House
Upper Newtownards Road
Belfast BT4 3SB
Telephone: 0232 524685

Further free copies of this leaflet may be obtained by writing to one of the Agriculture Departments indicated above.

Free copies of the leaflets

'A Short Guide for Dairy Farmers to the requirements of the EC Directive on Milk Hygiene (EC Directive 92/46)' and

'A Short Guide for Farmers producing and processing milk from Goats and Sheep to the requirements of the EC Directive on Milk Hygiene (EC Directive 92/46)'

may be obtained by writing to:

MAFF Publications
London SE99 7TP



News Release

Ministry of Agriculture, Fisheries & Food, Whitehall Place, London SW1A 2HH. Press Office: 071-270 8973. Out of hours: 071-270 8080. Fax: 071-270 8443.

291/94

26 July 1994

NEW MILK HYGIENE REGULATIONS

The Ministry of Agriculture, Fisheries and Food today issued consultative proposals to simplify the milk hygiene regulations which have been in existence for over 20 years. They will implement EC Milk Hygiene rules and replace most existing milk hygiene legislation.

The main features of the new proposals are:

- Registration of all farms producing cows, goats, sheep and buffalo milk which meet EC standards;
- Approval of dairy establishments handling milk and milk based products which meet EC standards;
- A duty on dairy establishments to identify and monitor critical points in their food production chain;
- Standards for raw milk and microbiological standards for dairy products;
- An EC health mark for all packaged dairy products meeting EC standards.

The Draft Regulations will implement EC Directives 92/46 and 92/47 but will not become law until amendments have been agreed in Brussels which will provide greater flexibility, particularly for small businesses.

Following the recommendation of the Richmond Committee, the Regulations will also extend the current microbiological standards for raw cows drinking milk to raw goat's and sheep's drinking milk. It is also proposed that the current heat treatment provisions for cream and ice cream should be retained.

Notes to Editors

1. The draft Regulations are accompanied by a Draft Compliance Cost Assessment (CCA) and draft Code of Practice.

2. Separate but similar regulations will be issued for consultation in Scotland and Northern Ireland shortly.

3. EC Directive 92/46 laying down health rules for production and placing on the market of raw milk, heat treated milk and milk-based products was agreed in June 1992 (OJ Reference L268 14.9.92). Directive 92/47 (OJ Reference L268 14.9.92) laying down conditions for granting temporary and limited derogations from specific requirements in Directive 92/46 was agreed at the same time.

4. The Richmond Committee report on the microbiological safety of food published by HMSO in 1991 (ISBN 011 321347 6) recommended that raw milk and milk products originating from sheep and goats should be subject to controls similar to those for raw cows milk and milk products.

5. The Regulations will replace most existing milk hygiene legislation namely:

Milk and Dairies (Channel Islands and South Devon Milk) Regulations 1956
Milk and Dairies (General) Regulations 1959 (except for Regulations 18-20)
Drinking Milk Regulations 1976
Milk-Based Drinks (Hygiene and Heat-Treatment) Regulations 1983
Milk and Dairies (Heat-Treatment of Cream) Regulations 1983
Milk and Dairies (Semi-Skimmed and Skimmed Milk) (Heat-Treatment and Labelling) Regulations 1988
Importation of Milk Regulations 1988
Milk (Special Designation) Regulations 1989

6. Labelling provisions are contained in the draft consolidated Food Labelling Regulations which have been subject to recent public consultation and which will also revoke the Milk and Dairies (Milk Bottle Caps) (Colour) Regulations 1976.

7. Comments on the proposals and the CCA should be sent to MAFF Milk and Milk Products Division, Branch C, Room 517, Whitehall Place East, London SW1A 2HH to arrive no later than 26 October 1994.

END